

**Project Title:**

Novel compliant scaffold with specific design for the treatment of non-thrombotic stenosis of internal jugular veins in patients with chronic headache poor responder to best medical therapy.

Project Code: CO-2018-12367503**Principal Investigator:** Veroux Pierfrancesco

Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...

Applicant Institution: Sicilia**Project Type: Industrial Co-financing/Progetti cofinanziati con industrie****Major Diagnostic Category*:** Neurologia**Project Classification IRG:** Brain Disorders and Clinical Neuroscience**Project Classification SS:** Clinical Neuroscience and Neurodegeneration - CNN**Project Keyword 1:** Changes in learning, memory, language, attention, behavior, and other functional domains that are consequences of disease.**Project Keyword 2:** Chronic Headache; Idiopathic Intracranial Hypertension**Project Keyword 3:** Non thrombotic Internal Jugular Veins obstructive diseases**Project duration (months):** 36**Project Request:** Animals: Humans: Clinical trial: **The object/s of this application is/are under patent copyright Y/N:** **Patent number:** European patent n° 1651/2914214**Type patent owner:** Private**Patent owner:** PIERFRANCESCO VEROUX**Operative Units / WP**

	INSTITUTION	Department/Division/Laboratory	Role in the project
1	Sicilia	Vascular Surgery and Organ Transplant Unit, Azienda Ospedaliera Universitaria Policlinico /VE di Catania	Coordination of the project, performing all the endovascular procedures, evaluation of results and outcomes
2	Neurology Unit	Azienda Ospedaliera Universitaria Policlinico /VE di Catania	Evaluation of patients with headache. Collection of data and analysis of follow up of all treated patients.

*(Data changed during the moratorium period)***Investigators, Institution and Role in the Project**

	Co-PI	Under40	Key Personnel	Institution/Org./Pos.	Role in the project	Birth Date
1			Reggio Ester	Neurology Unit	Evaluation of patients with headache. Collection of data and analysis of follow up of all treated patients.	14/06/1974
2	X		Veroux Massimiliano	Sicilia	Clinical evaluation of enrolled patients, performing the endovascular procedures, collection and analysis of data	28/09/1971
3		X	Giaquinta Alessia	Sicilia	Clinical evaluation of enrolled patients and performing the endovascular procedures.	30/09/1979

Industrial / Manufacturer Cofinancing

Industry/Manufacturer: Petalo srl

Address: VIA LUIGI RIZZO 18, 95131 CATANIA

City-State and Country: Catania- Sicilia - ITALY

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Amount cash co-financing: 427.000 euro

Contact Person: Name: GIANFRANCO BARBAGALLO Email: gianbar2000@yahoo.it Phone: 3356886018

Overall Summary

Chronic headache affect the 2-3% of general population. Idiopathic intracranial hypertension (IIH), has been involved in the development of chronic headache. In most of cases, IIH and chronic headache have been associated with a stenosis of the internal jugular vein (IJV). The endovascular treatments (balloon venoplasty and stenting) of non-thrombotic IJV stenosis have been proven to provide a significant short-term improvement of IIH and related headache, but data on long-term outcome are not satisfactory due to the high rate of recurrence.

The goal of this project is to evaluate, in a phase-II study, the safety and efficacy of an innovative venous-oriented device (Petalò CVS) in the treatment of patients with non-thrombotic internal jugular vein stenosis and chronic headache. A pre-clinical study have already demonstrated a favorable safety profile of Petalò CVS, and the novel configuration of the scaffold provided an excellent patency, even without the use of anticoagulant drugs.

Background / State of Art

Non-thrombotic obstructive venous diseases of the internal jugular veins(IJV), such as hypoplasia, intraluminal defects, and extrinsic compression, may have different hemodynamic effects on the cerebral venous system(1-3), and non-thrombotic IJV stenosis may be associated with many neurodegenerative disorders, including the multiple sclerosis (2-4). Chronic headache affect the 2-3% of general population(1) and is defined as of at least one headache episode for 15 days/month on average for >3 months. Recently, idiopathic intracranial hypertension (IIH), a disorder of elevated intracranial pressure of unknown cause occurring predominantly in young women of childbearing age, has been involved in the pathogenesis of chronic headache (6). In patients with chronic headache and IIH, a stenosis at the junction of the transverse and sigmoid sinuses has been recognized through venography but, recently, the role of isolated non-thrombotic IJV stenosis in IIH has gained a vested interest (6,7). Otherwise, the lack of alteration of cerebral venous outflow and the lack of elevated intracranial pressure values are identified in more than 50% of patients with chronic headache(8) and IIH with stenosis of the transverse sinuses may be present also in patients without chronic headache. Recent studies suggest that non-thrombotic stenosis of the internal jugular vein may worsen the headache clinical severity, suggesting a possible causative role in the pathogenesis of chronic headache(9). We have recently demonstrated (4) that the intervention of PTA was associated with a large and sustained(>3 years) improvement in clinical symptoms of patients with persistent headaches and selected concomitant obstructive disease of the IJVs. Although endovenous balloon angioplasty used for treating occlusive venous disease has a satisfactory safety profile, it may be characterized by a low patency and clinical improvement rates (2-3). Nevertheless, angioplasty of IJVs is complicated by a high rate of early stenotic recurrence, with incidence of restenosis between 30% and 50% of cases(2,8,10). Such high restenosis rates suggest that discussion of inadequate treatment may be more appropriate rather than restenosis or recurrence. Otherwise, stenting of IJVs showed a good efficacy profile with no immediate increase of risk. However, long-term results are not encouraging due to high rate of restenosis(10). Until recently, venous stenting has emerged as an attractive therapy with the potential of addressing the intracranial pressure elevation-associated clinical issues from etiological level, particularly after medical failure (5). The complications of stenting such as ipsilateral headache, restenosis, intra-stent thrombosis have been demonstrated in the settings of intracranial sinus obstruction, but very few studies investigated the role and efficacy of IJV stenting in the treatment of intracranial hypertension and headache. In a recent study, Zhou et al(7), found a subset of patients with presumed IIH with isolated IJV stenosis, which improved significantly their clinical symptoms(headache, tinnitus) after stenting of the IJV.

The current design of stents for the venous system, however, shows improved and continuous radial force and resistance to compression. The increasing diameter of vessel toward the heart requires an oversized stent diameter to avoid migration,



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and this could determine the loss of the physiological compliance of the vein(11).We have already evaluated in an animal model, the safety and efficacy of Petalo CVS, designed with full consideration of the collapsible nature of the vein, which is responsible for great variation in venous capacity with little change in venous pressure. Petalo was developed considering the main characteristics of the vein, that is, the delicate and elastic venous wall and the capacity to adapt its cross-sectional area to flow volume and pressure changes.This study documented a favorable safety profile of Petalo CVS.

It's available a Systematic Review on this topic? Si

It's available as publication please report bibliographic data? Si

Bibliographic data (DOI): 10.1016/j.ncl.2016.08.004

Hypotesis and Specific AIMS

Hypotesis and Significance:

Headache and Idiopathic intracranial hypertension (IIH) may be associated with a non-thrombotic stenosis of internal jugular veins(IJVs) in a significant proportion of patients. Endovenous balloon angioplasty may provide a sustained improvement in clinical symptoms of patients with persistent headaches and selected concomitant obstructive disease of the IJVs, but long-term outcomes are affected by a high rate of restenosis or recurrence. Recent studies suggested the potential role of venous stenting in the treatment of IJV stenosis, but the available devices are associated with a high rate of restenosis. Petalo, a new compliant venous scaffold, was designed with full consideration of the collapsible nature of the vein and was associated with excellent patency rate in an animal model. Recent studies have shown that venous stenting could provide a significant short-term improvement in patients with headache and IIH and IJV stenosis. We may anticipate that the use of this new device, specifically designed for the venous system, could significantly improve the symptom in patients with chronic headache and stenosis of IJV, with a very low rate of device-related complications.

Preliminary Data:

Venographic studies demonstrated that internal jugular vein stenosis may be associated with many neurological disorders, including the IIH and chronic headache (2,3,5,6). We have recently demonstrated (4) that the intervention of ballon venoplasty was associated with a large and sustained (>3 years) improvement in clinical symptoms of patients with persistent headaches and selected concomitant obstructive disease of the IJVs, and a recent study suggested the potential role of IJV stenting in the treatment of IIH-related headache not responsive to therapy (6).

We have evaluated in an animal model, the safety and efficacy of a new device, named Petalo CVS, designed with full consideration of the collapsible nature of the vein, (12, Project code CO-2011-02351787). Petalo has a tubular concave shape with 4 support modules joined by transverse bridges (Figure 1).The modules are oriented longitudinally and extend along the entire length of the device's body. The concavity of the four modules is oriented toward the vein wall. The support modules are internally empty, without bridges or other internal elements, to minimize the metal structure. Two transversal bridges join the support modules in the central part of the body, leaving the extremity of the modules free and open. The joined bridges enhance the conformability of the device and reduce the radial force. The concave shape of the support modules was studied to reduce the contact between the device and vein wall, with the aim of decreasing inflammatory. Petalo was evaluated in 12 healthy pigs. The study evaluated a composite of safety and efficacy endpoints. Petalo promoted only minimal response of the vein wall, with a primary patency of 100% and the patency of the target veins was maintained without the need of any specific anticoagulant therapy. The shape and configuration of this device avoid migration outside the target veins and fractures of the scaffold, despite the light structure and reduced radial force.



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Picture to support preliminary data:

Veroux Figure 1.jpg

Specific Aim 1:

To evaluate the incidence of internal jugular vein stenosis in patients with chronic headache not responsive to two medical treatments

Specific Aim 2:

To evaluate the safety profile of a novel compliant scaffold with specific design for the treatment of non-thrombotic stenosis of internal jugular veins (Petalò CVS).

Specific Aim 3:

To evaluate a composite secondary endpoint of device and clinical efficacy of a novel compliant scaffold with specific design for the treatment of non-thrombotic stenosis of internal jugular veins in patients with chronic headache

Experimental Design Aim 1:

This study will screen patients suffering from headache with age > 18 years not responsive to two medical treatments, with the diagnosis of chronic migraine or chronic tension-type headache according to the criteria of the International Classification of Headache Disorders (ICHD-3 beta) (13).

All patients will fill in a headache diary showing the number of days of headache per month and the main characteristics of headache attacks occurring during the previous 6 months before the enrollment and during all the study period. At the enrollment and at any control visit Migraine Disability Assessment questionnaire (MIDAS) will be administered in order to assess any variation of headache frequency and severity and the headache disability before and after treatment.

All patients will sign an informed consent, detailing all the procedures and the potential benefits and complications of the study procedures. All patients meeting the inclusion criteria will undergo a Duplex ultrasound (DUS) of their IJVs and/or an angio-MRI of extracranial vessels.

Exclusion criteria will be:

- Patients with unilateral stenosis or patients with IJV bilateral thrombosis,
- patients with IJV muscle compression and hypoplasia of IJVs
- presence of pace makers
- documented severe intolerance to contrast medium
- no compliance with therapy
- intracranial abnormalities such as tumor, abscess and vascular malformation
- severe hematological, hepatic or renal dysfunction(end-stage renal disease on dialysis will not be a contraindication)
- pregnant or lactating woman
- life expectancy < 1 year
- patients unlikely to be compliant with intervention

Patients with a DUS stenosis >50% of both IJVs will undergo a venous angiography of IJVs.

IJV morphologic and hemodynamic anomalies will be documented using in all patients a standardized, validated, operator-independent catheter venography protocol, as previously described (2,3). In particular we evaluate for the right and left IJVs the following factors determining stenosis >50% with respect to the proximal adjacent vein segment and associated with a moderate/severe delay in flow through the IJV:

- Anomalous valve with longitudinal defect;

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- An anomalous valve with transversal defect;
- Anomalous extrinsic muscular compression determining stenosis >80% .
- IJV hypoplasia with presence of collateral pathways.

In all patients we will use Intravascular Ultrasound to determine and confirm the presence of non-thrombotic stenosis and the size and diameters of the veins. In particular we will document the area and the different diameters of the veins in the site of stenosis, two centimeters above and below the stenotic area. Consequently, an overzise of 20-30% of the balloon or Petalo CVS will be used so avoiding an immediate ineffective treatment due to the use of a device with uncorrect diameter. In patients with no evidence of IJVs stenosis, the procedure will be concluded with the removal of the inguinal introducer, and no further treatment will be performed. All patients with documented IJVs stenosis will undergo randomization for venous stenting treatment versus placebo, as described in the experimental design 2.

Experimental Design Aim 2:

We expect to include in this study 50 patients. Patients undergoing venous angiography will be randomized in two groups on a 2:1 basis:

- patients undergoing stenting of IJVs (Group A)
- patients undergoing balloon venoplasty of IJVs(Group B)

In group A, all patients with internal jugular vein stenosis demonstrated by DUS and venous angiography, will undergo venous stenting of IJVs. During selective venography at least one device will be inserted at the site of stenosis using a standard pull-back stent delivery system. A new phlebography will be performed to evaluate the position of the device, the patency of the vein, and time of clearance of contrast medium as parameters of flow characteristics. The same procedure will be performed for the left jugular vein. At the end of the procedure, the inguinal introducer was removed, and light manual compression of the access site was performed.

In group B, a balloon venoplasty will be performed without proceeding to venous stenting.

The study will evaluate a composite of safety endpoints. The safety profile included successful delivery and positioning, rate of migration and fracture of the device, and rupture and bleeding of the target vein. Major adverse events (MAE) are defined as death, severe cardiac arrhythmia, and need for open surgery repair. The primary efficacy endpoints will be primary patency of the devices, absence of thrombus of the target IJV, persistent elasticity, and compliance of venous wall. Primary efficacy endpoints will be evaluated at 1, 3,6, and 12 months after the procedure. Outcomes endpoints will be evaluated with experimental aim 3.

Experimental Design Aim 3:

To determine the efficacy, we will evaluated these primary outcome measures:

- Correction of internal jugular vein stenosis

The status of internal jugular vein blood flow will be evaluated by Jugular Vein Doppler ultrasound at 1, 3,6 and 12 months after the procedure, in both groups. In patients with no clinical improvements or progressive worsening of headache, a venous angiography will be performed

- The evaluation of headache

The intensity of headache will be assessed in all patients with the Migraine Disability Assessment (MIDAS) (15) at baseline, at 1, 6 and 12 months after the treatment



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Methodologies and statistical analyses:

Statistical analysis will be performed using the respective MIDAS scores for the patient's pre and post-venous stenting. In order to facilitate meaningful statistical analysis, patients who experienced no headaches post-venous stenting will be given neutral MIDAS score of 0. Numerical data were presented as mean \pm SD, analyzed with the paired t test, or as median (interquartile range) analyzed by the non-parametric Wilcoxon signed-rank test if variables were not normally distributed. Categorical data were given as counts and percentages, which were compared using Fisher's exact tests. A two-tailed P value <0.05 was considered statistically significant. Statistical analysis of the data will be performed using in-house algorithms written in R (open source statistical software)

Expected outcomes:

The goal of this project is to evaluate the incidence of IJV stenosis in patients with chronic headache and the safety and efficacy of this new device in the treatment of this disease. We expect a negligible rate of procedure-related complications. We plan to use this device in 30 patients and we will evaluate the immediate complications related to the procedure such as collapse and migration to the heart. Twenty patients will be used as control group. We expect to find a relevant prevalence of internal jugular vein stenosis in patients with chronic headache, susceptible of venous stenting. We expect to treat 30 patients with venous stenting of internal jugular vein, which should result in a significant improvement of venous outflow and, consequently, in an improvement of headache and clinical symptoms in most patients. The particular shape and configuration of this device will assure a low rate of complications and satisfactory long-term outcomes.

Risk analysis, possible problems and solutions:

Risks of venous stenting of internal jugular vein in patients with chronic headache are not well known. However, the expertise of the research group in the endovascular procedures and the shape and configuration of this device will probably determine a low rate of procedure-related complications. Long-term complications, such as thrombosis of the stent, are not well known, but our preliminary data on the animal model are encouraging. It is possible that not all patients with chronic headache will be suitable for venous stenting, due to unfavorable anatomy of internal jugular vein. Our previous study demonstrated that younger patients with transversal endoluminal defects are more likely to experience a significant improvement in IJV outflow after venous angioplasty, whereas in older patients with IJV hypoplasia or longitudinal endoluminal defects, angioplasty is likely to have only a limited effect. In these patients it is likely that venous stenting will have a limited efficacy and the procedure will be evaluated on a case-by-case analysis.

Significance and Innovation

Recent studies suggest an important role of IJH in the pathogenesis of chronic headache, but most of the available treatments are directed only to alleviate the headache-related manifestations, with no influence on cerebral venous outflow, and high rate of recurrence. Venous stenting of IJV in patients with chronic headache and suitable anatomy could provide an efficacious and long lasting treatment for patients with headache. This study will probably provide a new alternative treatment for these patients, not just to alleviate the symptoms, but from a physiopathological point of view. The device that will be used in this research is highly innovative due to its specific design that respects the compliance of the veins wall and avoid migration. Moreover, the potential long term patency without the need of anticoagulant therapy, the very easy procedure of implantation and the possibility of performing all the procedures on a day-surgery basis, are the expected strengths of Petalo CVS.



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Description of the complementary and synergy research team

The Vascular Surgery and the Neurology Units have been collaborating for >5 years on the diagnostic evaluation and treatment of patients with many neurodegenerative disorders. Until recently, both research groups are collaborating on the definition of alternative and more efficacious treatment of chronic headache. There will be a high synergy and complementarity of the research group, since the clinical evaluation of patients with headache will be performed from Prof. Reggio together with the vascular surgeons and the planned treatment will be individualized basing on clinical and venography evaluation. Evaluation of outcomes of venous stenting will be evaluated from both neurologists (clinical evaluation) and vascular surgeons (morphological evaluation).

Training and tutorial activities

Due to its innovative fashion, this study will provide some important tools for the treatment of chronic headache. The evaluation of chronic headache may be easily translated to young fellows and to those who want to be more confident with these patients. Endovascular procedures will be performed in a technologically advanced angiographic hybrid operative room where surgeons in training can easily participate to the endovascular procedure. Moreover, all the operating rooms have an internet connection that makes possible to view all the procedures all over the world.



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Timeline / Deliverables / Payable Milestones

We plan to perform 50 procedures during the study period to evaluate the safety and efficacy of the device in patients with chronic headache not responsive to medical treatment. In the first 18 months we will complete the development of the device and we will perform the first 20 procedures of venous stenting and 10 venous angioplasty. We expect to standardize the procedure, with minimal procedure-related complications. We expect to have a 6-month follow-up for all ten patients enrolled in the first 18 months. We plan to perform 20 procedures in last 18 months and to complete the 1-year follow up for most patients, so that the collection of the data and statistical analysis will be performed., We will be able at the end of the study to evaluate the incidence of stenosis of IJV in patients with chronic headache and the efficacy of IJV stenting in the treatment of this disease.

Milestones 18 month

Within the first 18 months of this proposal we plan to achieve the following:

Complete the development of Petalo device.

Clinical evaluation (MIDAS) and evaluation by DUS and angiography of all patients. We plan to evaluate 30 patients with



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chronic headache. During the first 18 months we will be able to evaluate the incidence of stenosis of IJV in patients with chronic headache and to perform the venous stenting in 20 patients. Moreover, a 6-month follow up of treated patients will be available

Milestones 36 month

Between month 18 and 36 we plan to complete all the venous endovascular procedures in the remaining 20 patients and the 12-month follow up in all treated patients. Data on IJVs restenosis, short- and long-term complications, such as stent migration and/or thrombosis, and clinical outcomes will be available.

Gantt chart

gant chart.pdf

Equipment and resources available

All staff facilities, operating rooms, and laboratory equipment required to carry out the proposed studies are available at the University Hospital of Catania, where we have very considerable experience in the endovascular procedures for the treatment of venous obstructive diseases. There are two novel hybrid operating rooms, interconnected each other with the newest technological advancements and the possibility to clearly see all the procedures by a large screen inside the room. Moreover, all the operating rooms are connected with a wireless internet connection, so that all the procedures should be easily recorded and viewed in any computer from the same Hospital or all over the world. There are also all staff facilities at the Neurology Unit, where there is very considerable experience in the diagnosis and management of chronic headache. All the requested laboratory and radiology units including last generation of MRI, are all available at the University Hospital of Catania.

Translational relevance and impact for the National Health System (SSN)

Chronic headache affects the 2-3% of general population and available treatments may be, in many cases, ineffective with increased costs and patients inability to social activities. There are emerging evidences that chronic headache may be linked to a stenosis of internal jugular veins. This study will provide robust evidences of the impact of steno-obstructive venous disease in the pathogenesis of chronic headache, allowing for a targeted therapy. The number of patients eligible to the treatment with this new device is potentially high. This new device has the potential to reduce the rate of restenosis, a low rate of complications and expected better long-term outcomes in term of reduction of clinical symptoms. This will significantly reduce the costs for the treatment of chronic headache for the National Health System, allowing for most patients a return to daily activities.



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PRINCIPAL INVESTIGATOR PROFILE

Name	Institution	Sicilia
Veroux Pierfrancesco	Department/Unit	Chirurgia Generale e Specialità Medico Chirurgiche
	Position Title	FULL PROFESSOR OF VASCULAR SURGERY - UNIVERSITY OF CATANIA. HEAD of VASCULAR SURGERY AND ORGAN TRANSPLANTATION - AZIENDA OSPEDALIERA UNIVERSITARIA POLICLINICO / VE di CATANIA

Personal Statement

The goal of the project is to evaluate the safety profile and a composite of device and clinical efficacy of a novel compliant scaffold with specific design for the treatment of non thrombotic obstructive diseases of internal jugular veins in patients with chronic headache. I will be responsible for the overall coordination, development of the study and data interpretation with Prof. Veroux M, Reggio and Dr Giaquinta. As per my expertise, I will perform, with Dr Giaquinta and Veroux M., all the endovascular procedures and the evaluation, with Dr Reggio, of all patients affected by headache.

Education/Training - Institution and Location	Degree	Year(s)	Field of study
Klinische Abteilung für Transplantations Chirurgie, Universitätsklinik für Chirurgie Innsbruck, head prof. Raimond Margreiter	Senior Fellow	2002	Residency in Solid Organ Transplantation from 2001 to 2002 - Innsbruck
Service de Chirurgie Vasculaire de l'Hospital S. Joseph de Paris, head Prof. Jean Michel Cormier	Resident Etranger	1992	Residency in vascular surgery from 1990 to 1992- Paris - France
School of Medicine, University Hospital of Catania, Italy	Residency in Vascular Surgery	1996	Vascular Surgery
School of Medicine, University Hospital of Catania	Residency in General Surgery	1991	General Surgery
School of Medicine, University of Catania, Italy	MD	1986	Medicine and Surgery

**Project Title:**

Novel compliant scaffold with specific design for the treatment of non-thrombotic stenosis of internal jugular veins in patients with chronic headache poor responder to best medical therapy.

Project Code: CO-2018-12367503**Principal Investigator:** Veroux Pierfrancesco**Research Type:** a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...**Applicant Institution:** Sicilia**Project Type: Industrial Co-financing/Progetti cofinanziati con industrie**

Positions					
Institution	Division / Research group	Location	Position	From year	To year
Mayo Clinic	Mayo Clinic	Ronchester, USA	Visiting Professor	2013	2013
University of Bradford	University of Bradford	Bradford-United Kingdom	External examiner for Higher degrees	2014	2014
University of Catania	PhD in "Multidisciplinary Research in Advanced Organ Transplantation"	Catania, Italy	PhD Promoter and Coordinator	2010	2015
University of Catania	PhD in " Experimental Methods Research and Technological Application in Surgery"	Catania, Italy.	PhD Coordinator	2004	2014
National Transplant Center	Sicilian Transplant Center	Palermo-Sicily	Component of Regional Center for Organ Transplantation	2006	2012
University of Catania	Vascular Surgery and Organ Transplantation - Azienda Ospedaliera Universitaria Policlinico / VE	Catania, Italy	Director in Training School of Vascular Surgery for the south Italy	2007	2018
University of Catania	Vascular Surgery and Organ Transplantation - Azienda Ospedaliera Universitaria Policlinico / VE	Catania, Italy	Full Professor of Vascular Surgery	2006	2018
University of Catania	Vascular Surgery and Organ Transplantation - Azienda Ospedaliera Universitaria Policlinico / VE	Catania, Italy	Head of Vascular Surgery and Organ Transplant Unit	2004	2018
University of Catania	Vascular Surgery and Organ Transplantation - Azienda Ospedaliera Universitaria Policlinico / VE	Catania-Italy	Associated Professor in General Surgery	2001	2006

Official H index: 20.0 (autocertificated)**Source:** Scopus**Scopus Author Id:** 7004372833**ORCID ID:** <https://orcid.org/0000-0003-4965-7137>**RESEARCH ID:** K-5195-2018**Awards and Honors:**

Member of the executive council of the SICVE for the period 2010/13 and 2017-18

Member of the executive committee of the International Society of Neuro Vascular Disease from 2016 to now

President Elect of International Society of Neuro Vascular Disease from June 2018

Component of the board of "Abilitazione Scientifica Nazionale " of the Minister of the University of Italy

Principal Investigator of the winning project in the context of the FIR , University of Catania

Other CV Informations:

Teaches Vascular Surgery and Organ Transplantation in the Degree Course in Medicine and Surgery as well as in the

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Project Title: Novel compliant scaffold with specific design for the treatment of non-thrombotic stenosis of internal jugular veins in patients with chronic headache poor responder to best medical therapy.	
Project Code: CO-2018-12367503	Principal Investigator: Veroux Pierfrancesco
Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...	Applicant Institution: Sicilia
Project Type: Industrial Co-financing/Progetti cofinanziati con industrie	

Specialization Course at the University of Catania.

By Ministerial Decree Prof. Pierfrancesco Veroux has been authorized to carry out renal transplantations from cadavers, between living subjects and combined renal-pancreas transplantations.

By a Decree of the Councilor for Health of Sicily of 23/02/2006 Prof. Pierfrancesco Veroux was nominated as a member of the Commission for Humanitarian Medicine.

Principal Investigator of the project: development of a new endovascular device for the treatment of the large veins; Industrial co-financed; Bioengineering Sciences and Technologies of the "Ricerca finalizzata 2011-12 of the Italian Minister of Health".

**Project Title:**

Novel compliant scaffold with specific design for the treatment of non-thrombotic stenosis of internal jugular veins in patients with chronic headache poor responder to best medical therapy.

Project Code: CO-2018-12367503**Principal Investigator:** Veroux Pierfrancesco**Research Type:** a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...**Applicant Institution:** Sicilia**Project Type: Industrial Co-financing/Progetti cofinanziati con industrie****Selected peer-reviewed publications of the PI**

Valid for PI minimum expertise level				
Title	DOI	PMID	Cit. **	P.*
Kidney Transplantation From Hepatitis B Virus Core Antibody-Positive Donors: Prophylaxis With Hepatitis B Immunoglobulin. TRANSPLANTATION PROCEEDINGS, vol. 43, p. 967-970, ISSN: 0041-1345	doi: 10.1016/j.transproceed.2011.01.155	21620027	17	L
Pregnancy under everolimus-based immunosuppression. TRANSPLANT INTERNATIONAL, vol. 24, p. E115-E117, ISSN: 0934-0874	doi: 10.1111/j.1432-2277.2011.01356	21950359	27	L
New-onset diabetes mellitus after kidney transplantation: the role of immunosuppression. TRANSPLANTATION PROCEEDINGS, vol. 40, p. 1885-1887, ISSN: 0041-1345	doi: 10.1016/j.transproceed.2008.06.005	18675079	38	L
Infective complications in renal allograft recipients: epidemiology and outcome. TRANSPLANTATION PROCEEDINGS, vol. 40, p. 1873-1876, ISSN: 0041-1345	doi: 10.1016/j.transproceed.2008.05.065	18675076	61	L
Surveillance of human papilloma virus infection and cervical cancer in kidney transplant recipients: preliminary data. TRANSPLANTATION PROCEEDINGS, vol. 41, p. 1191-1194, ISSN: 0041-1345	NA	19460514	25	L
Long-term success of endovascular treatment of benign superior vena cava occlusion with chylothorax and chylopericardium	NA	12522636	12	F
Two-as-one monolateral dual kidney transplantation.	10.1016/j.urol.2010.02.024	20399490	17	F
Sexual dysfunction after elective endovascular or hand-assisted laparoscopic abdominal aneurysm repair.	10.1016/j.ejvs.2010.03.007	20403714	11	F
Age is an important predictor of kidney transplantation outcome	10.1093/ndt/gfr524	21926404	27	L
Mid-term sustained relief from headaches after balloon angioplasty of the internal jugular veins in patients with multiple sclerosis. PLOS ONE, vol. 13, ISSN: 1932-6203	doi: 10.1371/journal.pone.	29360844	2	L
Sirolimus-Based Immunosuppression in Kidney Transplantation for Type 2 Diabetic Nephropathy. UROLOGIA INTERNATIONALIS, vol. 84, p. 301-304, ISSN: 0042-1138	10.2217/imt.11.143	22091684	15	L
Visceral leishmaniasis in the early post-transplant period after kidney transplantation: clinical features and therapeutic management. TRANSPLANT INFECTIOUS DISEASE, vol. 12, p. 387-391, ISSN: 1398-2273	doi: 10.1111/j.1399-3062.2010.00520	20534033	24	L
Depression and quality of life in living related renal transplantation. TRANSPLANTATION PROCEEDINGS, vol. 39, p. 1791-1793, ISSN: 0041-1345	NA	17692614	48	L
Use of hepatitis B core anti body-positive donor kidneys in hepatitis B surface antibody-positive and -negative recipients. TRANSPLANTATION PROCEEDINGS, vol. 37, p. 2574-2575, ISSN: 0041-1345	doi: 10.1016/j.transproceed.2005.06.068	16182748	20	L
Monolateral Dual Kidney Transplantation From Marginal Donors	10.1016/j.transproceed.2007.05.042	17692617	17	L
Late complication from a retrievable inferior vena cava filter with associated caval, aortic, and duodenal perforation: A case report	10.1016/j.jvs.2008.02.002	18589238	36	L



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Project Title:

Novel compliant scaffold with specific design for the treatment of non-thrombotic stenosis of internal jugular veins in patients with chronic headache poor responder to best medical therapy.

Project Code: CO-2018-12367503

Principal Investigator: Veroux Pierfrancesco

Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...

Applicant Institution: Sicilia

Project Type: Industrial Co-financing/Progetti cofinanziati con industrie

Title	DOI	PMID	Cit. **	P. *
Internal jugular veins outflow in patients with multiple sclerosis: A catheter venography study	10.1016/j.jvir.2013.08.024	24409471	16	F
Primary balloon angioplasty of small (<2 mm) cephalic veins improves primary patency of arteriovenous fistulae and decreases reintervention rates	10.1016/j.jvs.2012.07.047	23153423	12	F
Early de novo neoplasia after renal transplantation. TUMORI, vol. 89(4 Suppl), p. 301-304, ISSN: 0300-8916	NA	15110643	27	L
Efficacy of a novel method of intravenous infusion of the prostaglandin analogue iloprost for the treatment of lower-limb critical ischemia: An open-label, nonrandomized study in two cohorts. CURRENT THERAPEUTIC RESEARCH-CLINICAL AND EXPERIMENTAL, vol. 65, p. 255-265, ISSN: 0011-393X	doi: 10.1016/S0011-393X(04)80067-5	24672081	11	F

* Position: F=First L=Last C=Corrispondent

** Autocertificated



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Project Title:

Novel compliant scaffold with specific design for the treatment of non-thrombotic stenosis of internal jugular veins in patients with chronic headache poor responder to best medical therapy.

Project Code: CO-2018-12367503

Principal Investigator: Veroux Pierfrancesco

Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...

Applicant Institution: Sicilia

Project Type: Industrial Co-financing/Progetti cofinanziati con industrie

For evaluation CV			
Title	DOI	PMID	Cit. *
Efficacy and safety of extracranial vein angioplasty in multiple sclerosis: A randomized clinical trial. JAMA NEUROLOGY, vol. 75, p. 35-43, ISSN: 2168-6149	doi: 10.1001/jamaneurol.2017.3825	29150995	6
Factors influencing the hemodynamic response to balloon angioplasty in the treatment of outflow anomalies of internal jugular veins. JOURNAL OF VASCULAR SURGERY: VENOUS AND LYMPHATIC DISORDERS, vol. 5, p. 777-788, ISSN: 2213-333X,	doi: 10.1016/j.jvs.2017.0	29037345	2
Novel Compliant Scaffold with Specific Design for Venous System: Results of a Porcine Model Study. BIOMED RESEARCH INTERNATIONAL, vol. 2018, p. 1-8, ISSN: 2314-6133,	doi: 10.1155/2018/73123	29662897	0
Mid-term sustained relief from headaches after balloon angioplasty of the internal jugular veins in patients with multiple sclerosis. PLOS ONE, vol. 13, ISSN: 1932-6203,	doi: 10.1371/journal.pone.	29360844	1
Long-term success of endovascular treatment of benign superior vena cava occlusion with chylothorax and chylopericardium	10.1007/s00330-002-1556-2	12522636	12
Primary balloon angioplasty of small (<2 mm) cephalic veins improves primary patency of arteriovenous fistulae and decreases reintervention rates	10.1016/j.jvs.2012.07.047	23153423	12
Internal jugular veins outflow in patients with multiple sclerosis: A catheter venography study	10.1016/j.jvir.2013.08.024	24409471	16
Multiple sclerosis and CCSVI: A population-based case control study	10.1371/journal.pone.0041227	22870210	20
Status update and interim results from the asymptomatic carotid surgery trial-2 (ACST-2)	10.1016/j.ejvs.2013.07.020	24051108	29
Late complication from a retrievable inferior vena cava filter with associated caval, aortic, and duodenal perforation: A case report	10.1016/j.jvs.2008.02.002	18589238	36

* Autocertificated

Grant			
Funded Institution / Country	Year	Title	Position in Projects
University of Catania	2014	Valutazione della vitalita' delle insule pancreatiche trapiantate nella sottomucosa gastrica delle scimmie: uno studio pre-clinico	Coordinator
Ministero della Salute	2011-12	Development of a new endovascular device for the treatment of occlusive disease of large veins (CO:2011-02351787)	Coordinator

Employment contract extension:

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BANDO RICERCA FINALIZZATA 2018
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Project Title: Novel compliant scaffold with specific design for the treatment of non-thrombotic stenosis of internal jugular veins in patients with chronic headache poor responder to best medical therapy.	
Project Code: CO-2018-12367503	Principal Investigator: Veroux Pierfrancesco
Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...	Applicant Institution: Sicilia
Project Type: Industrial Co-financing/Progetti cofinanziati con industrie	

(Data changed during the moratorium period)

**Project Title:**

Novel compliant scaffold with specific design for the treatment of non-thrombotic stenosis of internal jugular veins in patients with chronic headache poor responder to best medical therapy.

Project Code: CO-2018-12367503**Principal Investigator:** Veroux Pierfrancesco**Research Type:** a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...**Applicant Institution:** Sicilia**Project Type: Industrial Co-financing/Progetti cofinanziati con industrie****Biographical Sketch Contributors 1**

Name: Reggio Ester	Institution Neurology Unit
	Department/Unit Department of Medical and Surgical Sciences, University of Catania
	Position Title Researcher

Education/Training - Institution and Location	Degree	Year(s)	Field of study
University of Catania	PhD in Motor Sciences	3	Research activities in motor sciences and neurological disorders
University of Catania	Specialty School in Neurology	4	Residency in Neurology
University of Catania	Medicine and Surgery	6	Degree in Medicine and Surgery

Personal Statement:

The goal of the project is to evaluate the safety profile and a composite of device and clinical efficacy of a novel compliant scaffold with specific design for the treatment of non thrombotic obstructive diseases of internal jugular veins in patients with chronic headache. My role in the project deals with the screening of patients with headache in the phase of enrollment in order to classify the type of cephalgia according to the International Headache Classification; evaluate the enrolled patients in the pre-and post-treatment phases from a clinical and neurological point of view and on the basis of the Migraine Disability Assessment questionnaire (MIDAS) in order to assess any variation of headache frequency, severity and disability before and after treatment.

Institution	Division / Research group	Location	Position	From year	To year
Azienda Ospedaliero Universitaria Policlinico Vittorio Emanuele di Catania	Operative Unit of Neurology	Catania, Italy	Reseracher	2004	2018

Awards and Honors**Official H index:** 19.0 (autocertificated)**Source:** Scopus**Scopus Author Id:** 6601999993**ORCID ID:** <https://orcid.org/0000-0002-7350-6956>**RESEARCH ID:** K-5415-2018**Awards and Honors:**

Acknowledgment for best poster at American Academy in 2004

(Data changed during the moratorium period)



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BANDO RICERCA FINALIZZATA 2018
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Project Title:

Novel compliant scaffold with specific design for the treatment of non-thrombotic stenosis of internal jugular veins in patients with chronic headache poor responder to best medical therapy.

Project Code: CO-2018-12367503

Principal Investigator: Veroux Pierfrancesco

Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...

Applicant Institution: Sicilia

Project Type: Industrial Co-financing/Progetti cofinanziati con industrie

Biographical Sketch Contributors 2

Name: Veroux Massimiliano	Institution	Sicilia
	Department/Unit	Department of Medical and Surgical Sciences and Advanced technologies GF Ingrassi University of Catania
	Position Title	Associate Professor of Surgery, University of Catania

Education/Training - Institution and Location	Degree	Year(s)	Field of study
School of Medicine, University of Catania, Italy	PhD	3	Traumatology and Surgical Sciences
School of Medicine, University of Catania, Italy	Residency	5	General Surgery
School of Medicine, University Hospital of Catania, Italy	MD	6	Medicine and Surgery

Personal Statement:

The goal of the project is to evaluate the safety profile and a composite of device and clinical efficacy of a novel compliant scaffold with specific design for the treatment of non thrombotic obstructive diseases of internal jugular veins in patients with chronic headache. My role in the project is to perform endovascular procedures, together with Prof. Pierfrancesco Veroux and Dr Alessia Giaquinta, and to collect and analyze the data of all patients enrolled in the study. Moreover, i will be the co-PI of the project.

**Project Title:**

Novel compliant scaffold with specific design for the treatment of non-thrombotic stenosis of internal jugular veins in patients with chronic headache poor responder to best medical therapy.

Project Code: CO-2018-12367503**Principal Investigator:** Veroux Pierfrancesco**Research Type:** a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...**Applicant Institution:** Sicilia**Project Type: Industrial Co-financing/Progetti cofinanziati con industrie**

Institution	Division / Research group	Location	Position	From year	To year
University of Catania, school of Medicine	School of Medicine, University of Catania	Catania, Italy	Doctor in Medicine	1989	1995
University of Catania	Surgical Unit	Catania, Italy	Resident in General Surgery	1995	1999
University of Padua	Liver Transplant Unit, Department of Surgery and Gastroenterological Sciences, University of Padua	Padua, Italy	Resident in General Surgery	1999	2000
University Hospital of Catania	Organ Transplant Unit, Department of Surgery, Transplantation and Advanced Technologies, University of Catania	Catania, Italy	PhD in Traumatology	2000	2003
University Hospital	Vascular Surgery and Organ Transplant Unit, Department of Surgery, transplantation and Advanced technologies, University of Catania	Catania, Italy	Consultant Surgeon	2003	2007
University of Hospital of Catania	Vascular Surgery and Organ Transplant Unit, Department of Medical and Surgical Sciences, and Advanced Technologies, University of Catania	Catania, Italy	Associate Professor of Surgery	2007	2018

Awards and Honors**Official H index:** 22.0 (autocertificated)**Source:** Scopus**Scopus Author Id:** 7003920425**ORCID ID:** <https://orcid.org/0000-0002-2780-6421>**RESEARCH ID:** K-4821-2018**Awards and Honors:**

2012 Grant: "The Gastric submucosal Space..."Progetto di Ricerca Finalizzata del Ministero della Salute(PE-2011-02350135 €. 395.209,16)

2011Honorary Diploma in Transplantation Surgery from the European Board of Surgery

2010Clin Infect Dis Award for Outstanding Review

2006-2007Hesperis Diploma from ESOT

2004Biography inserted in 2003-2004 Who's Who in Medicine and healthcare

2003Award from Consorzio Interuniversitario Trapianti d'organo

2001Ettore Ruggieri Award from Italian Society of Surgery

(Data changed during the moratorium period)

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Project Title:

Novel compliant scaffold with specific design for the treatment of non-thrombotic stenosis of internal jugular veins in patients with chronic headache poor responder to best medical therapy.

Project Code: CO-2018-12367503

Principal Investigator: Veroux Pierfrancesco

Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...

Applicant Institution: Sicilia

Project Type: Industrial Co-financing/Progetti cofinanziati con industrie

**Project Title:**

Novel compliant scaffold with specific design for the treatment of non-thrombotic stenosis of internal jugular veins in patients with chronic headache poor responder to best medical therapy.

Project Code: CO-2018-12367503**Principal Investigator:** Veroux Pierfrancesco**Research Type:** a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...**Applicant Institution:** Sicilia**Project Type: Industrial Co-financing/Progetti cofinanziati con industrie****Biographical Sketch Contributors 3**

Name: Giaquinta Alessia	Institution Sicilia
	Department/Unit Vascular Surgery and Organ Transplantation - Azienda Ospedaliera Universitaria Policlinico / VE
	Position Title Clinical evaluation of enrolled patients and performing the endovascular procedures.

Education/Training - Institution and Location	Degree	Year(s)	Field of study
Vascular Surgery- University of Bologna. Head prof. Andrea Stella	Fellow	2010	Vascular Surgery
Vascular Surgery and Transplantation- University of Catania	Fellow	2009	International Living Donor kidney Transplantation Training _z
Vascular surgery Unit - University of Lille - France Head prof. Stephan Haulon	Fellow	2017	Advanced Endovascular Aortic training
Interventional Angiology-University of Leipzig - Germany Head Prof. Dierk Scheinert	Fellow	2017	Endovascular Surgery
School of Medicine, University Hospital of Catania, Italy	Residency in Vascular Surgery	2015	Vascular Surgery
School of Medicine, University of Catania, Italy	MD	2010	Medicine and Surgery

Personal Statement:

The goal of the project is to evaluate the safety profile and a composite of device and clinical efficacy of a novel compliant scaffold with specific design for the treatment of non thrombotic obstructive diseases of internal jugular veins in patients with chronic headache. My role in the project is to perform DUS evaluation of patients with headache and to perform endovascular procedures, together with Prof. Pierfrancesco Veroux and Prof. Massimiliano Veroux, and to collect and analyze the data of all patients enrolled in the study.

Institution	Division / Research group	Location	Position	From year	To year
Istituto G.Giglio	Vascular Surgery Unit	Cefalù, Palermo - Italy	Assistent I degree - vascular surgeon	2015	2016
Azienda Ospedaliero Universitaria Policlinico/VE	Vascular Surgery and Organ Transplantation Unit	Catania -Italy	Assistent I degree - vascular surgery	2016	2018
University of Catania	Translational Biomedicine	Catania - Italy	PhD - Medicine	2013	2016

Awards and Honors**Official H index:** 12.0 (autocertificated)**Source:** Scopus**Scopus Author Id:** 24478646300**ORCID ID:** <https://orcid.org/0000-0003-3227-4340>**RESEARCH ID:** K-5205-2018



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Project Title:

Novel compliant scaffold with specific design for the treatment of non-thrombotic stenosis of internal jugular veins in patients with chronic headache poor responder to best medical therapy.

Project Code: CO-2018-12367503

Principal Investigator: Veroux Pierfrancesco

Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...

Applicant Institution: Sicilia

Project Type: Industrial Co-financing/Progetti cofinanziati con industrie

Awards and Honors:

2015: Grant of the project: Development for a new endovascular device for the treatment of occlusive disease of large veins - Ricerca Finalizzata 2011 - Minister of Health.

2017: has been authorized to carry out renal and experimental uterus transplantations from cadavers donors - Vascular surgery and organ transplantation Unit - Azienda Ospedaliero Universitaria Policlinico-Vittorio Emanuele di Catania.

(Data changed during the moratorium period)

**Project Title:**

Novel compliant scaffold with specific design for the treatment of non-thrombotic stenosis of internal jugular veins in patients with chronic headache poor responder to best medical therapy.

Project Code: CO-2018-12367503**Principal Investigator:** Veroux Pierfrancesco**Research Type:** a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...**Applicant Institution:** Sicilia**Project Type: Industrial Co-financing/Progetti cofinanziati con industrie****Expertise Research Collaborators**

Selected peer-reviewed publications of the Research Group / Collaborators				
Collaborator	Title	DOI	PMID	Cit. *
Veroux Massimiliano	Laparoscopic treatment of simple hepatic cysts and polycystic liver disease	10.1007/s00464-002-9088-z	12574922	69
Veroux Massimiliano	Late complication from a retrievable inferior vena cava filter with associated caval, aortic, and duodenal perforation: a case report	10.1016/j.jvs.2008.02.002	18589238	36
Veroux Massimiliano	Risk of de novo cancers after transplantation: results from a cohort of 7217 kidney transplant recipients, Italy 1997-2009	10.1016/j.ejca.2012.09.013	23062667	67
Veroux Massimiliano	Status update and interim results from the asymptomatic carotid surgery trial-2 (ACST-2).	10.1016/j.ejvs.2013.07.020	24051108	29
Reggio Ester	Safety and efficacy of eculizumab in anti-acetylcholine receptor antibody-positive refractory generalised myasthenia gravis (REGAIN): a phase 3, randomised, double-blind, placebo-controlled, multicentre study.	10.1016/S1474-4422(17)30369-1	29066163	8
Reggio Ester	Stabilization of rapidly worsening multiple sclerosis for 36 months in patients treated with interferon beta plus cyclophosphamide followed by interferon beta.	10.1007/s00415-004-0581-2	15645351	24
Reggio Ester	Relationship between clinical variables and cognitive performances in migraineurs with and without aura.	NA	15274516	21
Reggio Ester	The impact of outpatient rehabilitation on quality of life in multiple sclerosis.	10.1007/s00415-002-0778-1	12195449	82
Reggio Ester	Combination of cyclophosphamide and interferon-beta halts progression in patients with rapidly transitional multiple sclerosis.	NA	11511721	45
Reggio Ester	Memory disturbances in migraine with and without aura: a strategy problem?	10.1046/j.1468-2982.2000.00074.x	11037744	66

* Autocertificated

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Project Title:

Novel compliant scaffold with specific design for the treatment of non-thrombotic stenosis of internal jugular veins in patients with chronic headache poor responder to best medical therapy.

Project Code: CO-2018-12367503

Principal Investigator: Veroux Pierfrancesco

Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...

Applicant Institution: Sicilia

Project Type: Industrial Co-financing/Progetti cofinanziati con industrie

Grant				
Funded Institution / Country	Year	Title	Position in Projects	Collaborator
University of Udine	2017	Indagine multicentrica su conoscenze attitudini, e comportamenti dei pazienti dializzati in riferimento alla vaccinazione anti-influenzale.	Collaborator	Veroux Massimiliano
University Of Catania	2014	Screening for colo-rectal carcinoma in kidney transplant recipients: clinical and psychological perspectives	Coordinator	Veroux Massimiliano
Ministero della salute	2011-12	The Gastric submucosal Space and lymph nodes as alternative sites for islet allo-transplantation using clinically applicable immunosuppression	Coordinator	Veroux Massimiliano



Ministero della Salute
Direzione Generale della Ricerca Sanitaria
e Biomedica e della Vigilanza sugli Enti

BANDO RICERCA FINALIZZATA 2018
esercizio finanziario anni 2016-2017

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Applicant Institution: Sicilia

Project Type: Industrial Co-financing/Progetti cofinanziati con industrie

Total proposed budget (Euro)				
Costs	TOTAL BUDGET	Co-Funding	List of costs proposed for funding to the MOH	Percentage of total proposed to the MOH
1a Staff Salary	40.000,00			0,00
1b Researchers' Contracts	228.000,00	34.000,00	194.000,00	46,41
2 Equipment (Leasing - Rent)	0,00	0,00	0,00	0,00
3a Supplies	555.000,00	360.000,00	195.000,00	46,65
3b Model Costs	0,00	0,00	0,00	0,00
3c Subcontracts	0,00	0,00	0,00	0,00
3d Patient Costs	15.000,00	9.000,00	6.000,00	1,44
4 IT Services and Data Bases	4.000,00	1.000,00	3.000,00	0,72
5 Publication Costs	5.000,00	2.000,00	3.000,00	0,72
6 Convegni	4.000,00	2.000,00	2.000,00	0,48
7 Travels	7.000,00	4.000,00	3.000,00	0,72
8 Overheads	17.000,00	10.000,00	7.000,00	1,67
9 Coordination Costs	10.000,00	5.000,00	5.000,00	1,20
Total	885.000,00	467.000,00	418.000,00	100,00

Report the Co-Funding Contributor:

Staff Salary: Proff. Pierfrancesco Veroux, Massimiliano Veroux, Ester Reggio and Dr Alessia Giaquinta
Petalò srl 427.000 euro

(Data changed during the moratorium period)

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Applicant Institution: Sicilia

Project Type: Industrial Co-financing/Progetti cofinanziati con industrie

Budget Justification

1a Staff Salary	Prof. Pierfrancesco Veroux, Prof. Massimiliano Veroux, Prof. Ester Reggio and Dr Alessia Giaquinta salary
1b Researchers' Contracts	Researcher contracts will be dedicated to the development of the project, and particularly for evaluation of the safety of the device, to the evaluation of headache in enrolled patients and to collection and analysis of data
2 Equipment (Leasing - Rent)	NA
3a Supplies	Prototype development and production and product verification & validation batch. Costs for device production and Miscellaneous Operating Room costs. Cost for MIDAS evaluation
3b Model Costs	NA
3c Subcontracts	NA
3d Patient Costs	travel and accomodation expenses for patients enrolled in the study
4 IT Services and Data Bases	Azienda Policlinico has a full equipment of IT services. Budget will be utilized for update the software and to create a dedicated data base
5 Publication Costs	All data accumulated from the study will be presented at national and international meetings, as well as we will report the data in form of peer-reviewed manuscripts in international journals
6 Convegni	registration fees to national and international congresses to present the results of the study
7 Travels	travel and accomodation expenses to partecipate to national and international congresses
8 Overheads	this will cover the institutional administrative costs fo operating room facilities, radiology and laboratory facilities
9 Coordination Costs	this will cover the congress organization, and the administrative costs of the project

(Data changed during the moratorium period)

**Project Title:**

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Research Type: a) Theory-enhancing: sviluppare procedure altamente innovative e nuove conoscenze utili al miglioramento delle opportunità di prevenzione, diagnosi, trattamento, riabilitazione anche attraverso...

Applicant Institution: Sicilia**Project Type: Industrial Co-financing/Progetti cofinanziati con industrie**

Proposed total budget UO1 Institution: Sicilia (Euro)

Costs	TOTAL BUDGET	Co-Funding	List of costs proposed for funding to the MOH	Percentage of total proposed to the MOH
1a Staff Salary	30.000,00			0,00
1b Researchers' Contracts	114.000,00	0,00	114.000,00	35,51
2 Equipment (Leasing - Rent)	0,00	0,00	0,00	0,00
3a Supplies	540.000,00	350.000,00	190.000,00	59,19
3b Model Costs	0,00	0,00	0,00	0,00
3c Subcontracts	0,00	0,00	0,00	0,00
3d Patient Costs	10.000,00	9.000,00	1.000,00	0,31
4 IT Services and Data Bases	3.000,00	1.000,00	2.000,00	0,62
5 Publication Costs	4.000,00	2.000,00	2.000,00	0,62
6 Convegni	3.000,00	2.000,00	1.000,00	0,31
7 Travels	5.000,00	4.000,00	1.000,00	0,31
8 Overheads	15.000,00	10.000,00	5.000,00	1,56
9 Coordination Costs	10.000,00	5.000,00	5.000,00	1,56
Total	734.000,00	413.000,00	321.000,00	100,00

Report the Co-Funding Contributor:

(Data changed during the moratorium period)

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Principal Investigator: Veroux Pierfrancesco

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Applicant Institution: Sicilia

Project Type: Industrial Co-financing/Progetti cofinanziati con industrie

Budget Justification	
1a Staff Salary	Prof. Pierfrancesco Veroux, Prof. Massimiliano Veroux and Dr Alessia Giaquinta salary
1b Researchers' Contracts	A researcher contract will be dedicated to the development of the project, and particularly for evaluation of the safety of the device
2 Equipment (Leasing - Rent)	NA
3a Supplies	Prototype development and production and product verification & validation batch. Costs for device production and Miscellaneous Operating Room costs
3b Model Costs	NA
3c Subcontracts	NA
3d Patient Costs	travel and accomodation expenses for patients enrolled in the study
4 IT Services and Data Bases	University of Catania has a full equipment of IT services. Budget will be utilized for update the software and to create a dedicated data base
5 Publication Costs	All data accumulated from the study will be presented at national and international meetings, as well as we will report the data in form of peer-reviewed manuscripts in international journals
6 Convegni	registration fees to national and international congresses to present the results of the study
7 Travels	travel and accomodation expenses to participate to national and international congresses
8 Overheads	this will cover the institutional administrative costs for operating room facilities
9 Coordination Costs	this will cover the congress organization, and the administrative costs of the project

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Proposed total budget UO2 Institution: Neurology Unit (Euro)

Costs	TOTAL BUDGET	Co-Funding	List of costs proposed for funding to the MOH	Percentage of total proposed to the MOH
1a Staff Salary	10.000,00			0,00
1b Researchers' Contracts	114.000,00	34.000,00	80.000,00	82,47
2 Equipment (Leasing - Rent)	0,00	0,00	0,00	0,00
3a Supplies	15.000,00	10.000,00	5.000,00	5,15
3b Model Costs	0,00	0,00	0,00	0,00
3c Subcontracts	0,00	0,00	0,00	0,00
3d Patient Costs	5.000,00	0,00	5.000,00	5,15
4 IT Services and Data Bases	1.000,00	0,00	1.000,00	1,03
5 Publication Costs	1.000,00	0,00	1.000,00	1,03
6 Convegni	1.000,00	0,00	1.000,00	1,03
7 Travels	2.000,00	0,00	2.000,00	2,06
8 Overheads	2.000,00	0,00	2.000,00	2,06
9 Coordination Costs				0,00
Total	151.000,00	54.000,00	97.000,00	100,00

Report the Co-Funding Contributor:

(Data changed during the moratorium period)

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Applicant Institution: Sicilia

Project Type: Industrial Co-financing/Progetti cofinanziati con industrie

Budget Justification	
1a Staff Salary	Prof. Ester Reggio Salary
1b Researchers' Contracts	Researcher contracts will be dedicated to the development of the project, and particularly for the evaluation of headache in enrolled patients and to collection and analysis of data
2 Equipment (Leasing - Rent)	NA
3a Supplies	Costs for MIDAS evaluation
3b Model Costs	NA
3c Subcontracts	NA
3d Patient Costs	travel and accomodation expenses for patients enrolled in the study
4 IT Services and Data Bases	Azienda Policlinico had a full equipment of IT services. Budget will be utilized for update the existing software and to create a dedicated data base.
5 Publication Costs	All data accumulated from the study will be presented at national and international meetings, as well as we will report the data in from of peer-reviewed manuscripts in international journals
6 Convegni	registration fees to national and international congresses for the presentation of the study
7 Travels	travel and accomodation expenses to partecipate to national and international congresses
8 Overheads	this will cover the institutional administrative costs for radiology and laboratory facilities
9 Coordination Costs	NA



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Applicant Institution: Sicilia

Project Type: Industrial Co-financing/Progetti cofinanziati con industrie

Principal Investigator Data

Cognome: Veroux

Nome: Pierfrancesco

Codice fiscale: VRXPFR61L14C351L

Documento: Passaporto, Numero: YA3484398

Data di nascita: 14/07/1961

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Qualifica: Direttore Struttura Complessa - Dirigente medico II livello-Professore Ordinario

Struttura: Struttura Complessa di Chirurgia Vascolare e Centro Trapianti

Istituzione: Azienda Ospedaliero Universitaria Policlinico/ Vittorio Emanuele di Catania-