VIRTUS - OUS
Safety and Efficacy of the Veniti Vici* Venous Stent System (Veniti Inc.) when Used to Treat Clinically Significant Chronic Non-malignant Obstruction of the Iliofemoral Venous Segment

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The objective of this study is to assess the safety and efficacy of the Veniti Vici* Venous Stent System in achieving patency of the target venous lesion through 36 months in patients who present with clinically significant chronic non-malignant...

Ethical review	Approved WMO
Status	Pending
Health condition type	Arteriosclerosis, stenosis, vascular insufficiency and necrosis
Study type	Interventional

Summary

ID

NL-OMON40842

Source
ToetsingOnline

Brief title
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Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
venous insufficiency, venous occlusion

Research involving

Human

Sponsors and support

Primary sponsor: Veniti, Inc.
Source(s) of monetary or material Support: Veniti;Inc.

Intervention

Keyword: Efficacy, Iliofemoral vein, Safety, Stent

Outcome measures

Primary outcome

The primary efficacy endpoint for this study will be the primary patency rate at 12 months post-intervention, defined as freedom from occlusion by thrombosis AND freedom from surgical or endovascular intervention on target vessel segment which are found to have re-stenosis or stent occlusion to maintain patency AND freedom from in-stent stenosis more than 50% by venogram and/or DUS .

The primary safety endpoint for this study will be a composite endpoint of any major adverse event within 30 days, as adjudicated by a Clinical Events Committee. Major Adverse Events include:

* Procedure or device-related death

* Procedure related bleeding requiring surgical or endovascular intervention or blood transfusion >=2 units

* Procedure related arterial or venous injury requiring surgical or endovascular intervention

* Device or procedure related acute DVT

* Clinically significant pulmonary embolism defined as being symptomatic with

chest pain, hemoptysis, dyspnea, hypoxia etc. AND be documented on CT

* Embolization of stentt

Secondary outcome

The formal secondary endpoint for this study will be a binary response variable based on an improvement in VCSS by at least 50% at 12 months post-intervention.

Ancillary Analyses

Procedural Endpoints

* Procedural technical success, defined as achievement of a final residual diameter stenosis of <=50% as measured by venogram without skipped lesion areas with placement of the study device alone with or without post-stenting balloon dilation
* Lesion success defined as achievement of <=50% residual diameter stenosis using any percutaneous method (including use of non-study devices)
* Procedural success defined as procedural technical success without the occurrence of major adverse event between the index procedure and discharge

Late technical success (through 12 months) defined as:

* Absence of migration from site of original placement such that target lesion is uncovered or results in separation of overlapping stents
* Absence of stent embolization
* Achievement of primary patency
* Structural integrity, defined as the absence of:
* Pinching, defined as focal compression of the stent with > 50% diameter

reduction of the stent

* Kinking, defined as >50% diameter reduction of the stent with the stent doubling or bending on itself

* Recoil, defined a poor radial resistance to diffuse collapse, which results in >50% diameter reduction of the stent (i.e., stent diameters obtained throughout the study period as compared to the final stent diameter after insertion measured by DUS or venogram).

* Fracture(s)

Fractures will be assessed as per Jaff, et al. 1 (See Appendix 3.) Data to be collected for each fracture identified includes:

o Limb (right or left)

o Venous segment(s) where fractures are located

o Overlapping versus non-overlapping

o Type of fracture (Type I, II, III, IV)

Study description

Background summary

Chronic venous disorders (CVD) have a significant social and economic cost, impacting an estimated 50% of Western populations, and consuming an estimated 2-3% of healthcare budgets. Percutaneous stenting of the iliofemoral venous outflow system has developed over the past decade as the *method of choice* to manage chronic venous obstruction. The procedure can be performed with low morbidity, no mortality, long-term high patency rate, and low rate of in-stent restenosis. It has replaced bypass surgery as the primary treatment.

Study objective

The objective of this study is to assess the safety and efficacy of the Veniti Vici* Venous Stent System in achieving patency of the target venous lesion

through 36 months in patients who present with clinically significant chronic non-malignant obstruction of the iliofemoral venous outflow tract.

Study design

Prospective, multicenter, single arm, non-randomized study to define safety and efficacy of the Veniti Vici* Venous Stent System in relation to pre-defined Objective Performance goals.

Intervention

Percutaneous placement of the Veniti Vici Venous Stent System.

Study burden and risks

Possible complications that the subject may experience from participating in this study include the following:
• A narrowing or scarring of the vein
• Complications (bleeding, bruising, pain, tenderness) where the study doctor enters your vein
• Damage to the vein that the study doctor punctures, or damage to the nearby artery and nerves
• A blood clot
• An allergic reaction to the dye used during the procedure
• A blood clot that travels to your lung
• Problems with kidney function
• Death
• An air bubble or other object carried in the bloodstream
• Emergency surgery to repair a damaged vein
• Higher or lower blood pressure
• Infection
• An infection in your lungs called pneumonia
• A collapsed lung
• A large collection of blood that forms as the result of a leaking hole in an artery
• Swelling of the vein caused by a blood clot
• A heart attack
• Chest Pain
• Movement of the investigational device from the original location where the study doctor placed it
• Increased bleeding risk from medications used to prevent blood clots

This study involves exposure to a very small amount of radiation. As part of everyday living, everyone is exposed to naturally occurring background radiation and receives a dose of about 2 millisieverts (mSv) each year. The dose from this study is comparable to the dose received from many diagnostic

medical X-ray and nuclear medicine procedures. At this dose level, no harmful effects of radiation have been demonstrated, as any effect is too small to measure.

Pregnant and breastfeeding women are excluded from this study. This applies to the entire study. It is not known what the consequences of participating in the study are to your unborn child.
The study doctor will discuss the procedure and the potential complications extensively discuss with the patient.

Benefits
There is no guarantee that one will benefit from participating in this study.
Potential benefits for patients in whom the device is implanted, include the following:
• improves their condition because blood can flow through a previously obstructed artery
• minimally invasive
• short-term hospital
This research may also mean an improvement for the future treatment of veuneuze failure at the height of the vein iliofemorale.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Age >=18 years
2. Willing and capable of complying with all follow-up evaluations at the specified times
3. Able and willing to provide written informed consent prior to study specific procedures
4. Presence of unilateral, clinically significant, chronic non-malignant obstruction of the common femoral vein, external iliac vein, common iliac vein, or any combination thereof, defined as a >=50% reduction in target vessel lumen diameter as measured by venogram
5. Clinically significant venous obstruction defined as meeting at least one of the following clinical indicators:
• Clinical severity class of CEAP classification >=3 (See Appendix 4.)
• VCSS Pain Score >=2 (See Appendix 7.)
6. Negative pregnancy test in females of child-bearing potential
7. Intention to stent the target lesion only with the Veniti Vici* Venous Stent

Exclusion criteria

1. Presence or history of clinically significant pulmonary emboli within 6 months prior to enrollment.
2. Venous obstruction that extends into the inferior vena cava
3. Contralateral disease of the common femoral vein, external iliac vein, common iliac vein, or any combination thereof with planned treatment within 30 days after subject enrollment
4. Life expectancy <12 months
5. Female of childbearing potential who is pregnant or plans to become pregnant during the duration of the clinical study
6. Uncontrolled or active coagulopathy or known uncorrectable bleeding diathesis
a. Uncorrected INR >=2.0 or aPTT >=1.5 X normal local lab value
b. Platelet count <100,000
c. Anti-platelet therapy except for ASA (patients on clopidogrel, prasugrel who cannot discontinue for seven days prior to the procedure are excluded)
7. Uncorrected hemoglobin of <=9 g/dL
8. Patients with an estimated glomerular filtration rate (eGFR) <30 mL/min
9. Known hypersensitivity to nickel or titanium
10. Contrast agent allergy that cannot be managed adequately with pre-medication
11. Intended concurrent thrombolysis or thrombectomy procedure OR intended or planned (within 30 days) adjuvant procedure such as creation of temporary AV fistula, placement of IVC filter, endovenectomy or saphenous vein ablation

12. Current or recent (within 30 days) active participation in another drug or device clinical trial
13. Patient judged to be a poor candidate by the primary investigator
14. Patient who does not consent to either the study treatment or study procedures, including follow-up visits
15. Patients who have had any prior surgical or endovascular procedure of the target vessel;Intra-procedural
1. Patients in whom the lesions cannot be traversed with a guide wire. These patients will not be enrolled and will not count against the study sample size.
2. Patients where the obstruction extends into the inferior vena cava. These patients will not be enrolled and will not count against the study sample size.
3. Patients whose vein diameters are not within limits stated in current Instructions for Use as determined by venogram. These patients will not be enrolled and will not count against the study sample size.
4. Patients who do not meet the venogram binary stenosis definition above, as determined by the treating physician.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2014
Enrollment:	10
Type:	Anticipated

Medical products/devices used

Generic name:	Veniti Vici Venous Stent System
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	04-08-2014
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	23-10-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT02112877
CCMO	NL49034.091.14