The BARD® VENOVO * Venous Stent Study - A Prospective, Non-Randomized, Multi-Center, Single-Arm Study of the Treatment of Iliofemoral Occlusive Disease * an Assessment for Effectiveness and Safety (VERNACULAR)

Published: 17-10-2016
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The objective of this study is to assess the safety and effectiveness of the VENOVO * Venous Stent for the treatment of iliofemoral occlusive disease including Acute or Chronic Deep Vein Thombosis (DVT), May-Thurner Syndrome, or any combination of...

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

Summary

ID

NL-OMON47346

Source
ToetsingOnline

Brief title
Venous Stent Study - VERNACULAR

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
Iliofemoral Occlusive Disease

Research involving

Human

Sponsors and support

Primary sponsor: C. R Bard
Source(s) of monetary or material Support: Bard Angiomed GmbH & Co

Intervention

Keyword: Stent, VENOVO

Outcome measures

Primary outcome

Safety:

Freedom from Major Adverse Events (MAEs) through 30 days

Defined as the following:

* Device and/or procedure related death

* Major amputation of target limb

* Pulmonary Embolism which is clinically important (symptomatic with chest

pain, hemoptysis, dyspnea, hypoxia, etc.)

* Target Vessel Revascularization (TVR)

* Vascular injury requiring surgical/endovascular intervention

* Embolization/migration of stent

* Device or procedure related acute DVT involving the treated limb

Efficacy:

Primary Patency rate at 12 months defined as

Freedom from TVR; freedom from thrombus occlusion and stenosis > 50% as

measured by DUS. Note: Venography will be used only if investigator cannot

successfully measure endpoint by DUS or if the investigator deems there is clinical need to perform invasive venography.

Secondary outcome

- Evaluation of VCSS Scores at 30 days, 6, 12, 24, and 36 months Quality of Life Questionnaire (QOL) at 30 days, 6, 12, 24, and 36 months

* Evaluation of CEAP Scores at 30 days, 6, 12, 24, and 36 months

* Acute Procedure Success

* Lesion Success

* Acute Technical Success

* Freedom From Target Lesion Revascularization (TLR) at 30 days 6, 24, 36 months

* Freedom From Target Vessel Revascularization (TVR) at 30 days, 6, 24, 36 months

* Primary Patency at 24, 36 months

* X-ray analysis for stent fracture at 12, 24, and 36 months

Study description

Background summary

The primary function of the veins within the circulatory system is to provide for the mechanism to return blood to the heart. Depending upon activity and posture, 60-80% of human resting blood resides within the venous system. Effective venous return requires the interaction of several components including gravity, arterial and capillary pressure, pumping action from surrounding skeletal muscle, and a system of venous valves which prevent retrograde flow (reflux) of blood. Calf muscle contraction drives the primary pump mechanism in the normal limb. This system of valves and efficient pump mechanisms work in concert to overcome the forces of gravity to aid in the return of blood to the heart.

The diagnosis and treatment of chronic venous disorders (CVD) has and continues to rapidly evolve. The CEAP (Clinical * Etiology * Anatomy * Pathophysiology) classification system provides for a standard measure to allow for the facilitation of meaningful communication about CVD and the treatment alternatives. The term chronic venous disorder (CVD) includes the full spectrum of morphological and functional abnormalities of the venous system from telangiectasias (discoloration of the skin due to chronic dilation of capillaries) to venous ulcers. Some of these, like telangiectasias, are highly prevalent in the
normal adult population, and in many cases the use of the term *disease* is not appropriate. The term chronic venous insufficiency (CVI) implies a functional abnormality of the venous system and usually is reserved for patients with more advanced disease including those with edema (C3), skin changes (C4), or venous ulcers (C5-6).This classification system, along with other quality of life measurement tools, will aid in the treatment of CVD.
Iliofemoral venous occlusive disease, often referred to as deep venous thrombosis (DVT) to distinguish it from thrombi of small, superficial veins in the extremities, occurs in the United States at annualized rates exceeding 249,000 cases. Post-thrombotic syndrome (PTS) is a serious complication of DVT. PTS is a specific subacute or chronic affliction caused by a combination of venous hypertension and valvular insufficiency manifested by pain, edema, vein dilation, and skin changes (pigmentation/ulceration). Imaging studies, especially Duplex Ultrasound (DUS), can be useful when the clinical picture is confusing or not obvious, but since there is no *gold standard* objective test to establish its presence, the diagnosis of Non-thrombotic iliac vein lesions (NIVL) need to be considered as contributing to the overall incidence of CVD. Although the prevalence of NIVL is widespread in the general population, the iliac compression syndrome known as May-Thurner is considered to be a relatively rare cause of CVD accounting for only 1-5% of the cases treated.

Study objective

The objective of this study is to assess the safety and effectiveness of the VENOVO * Venous Stent for the treatment of iliofemoral occlusive disease including Acute or Chronic Deep Vein Thombosis (DVT), May-Thurner Syndrome, or any combination of the above

Study design

This is a prospective, multi-center, non-randomized, single-arm clinical study of the VENOVO * Venous Stent for the treatment of iliofemoral occlusive disease. The study will be conducted at a maximum of 35 investigational sites (*sites*) in the United States, and Europe and Australia/New Zealand. Enrollment will continue until a maximum of one hundred seventy (170) subjects are treated with the VENOVO * Venous Stent, which is an estimated three-hundred forty (340) consecutive subjects in a non-randomized fashion. It is assumed that

approximately 50% of the treated subjects will be U.S. subjects.
Clinical follow-up for all treated subjects will be performed at hospital discharge, 30-days, and 6-, 12-, 24-, and 36-months post-index procedure.

Intervention

Patient will get the Venovo stent

Study burden and risks

NA

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. The subject provides written informed consent using an Informed Consent Form (ICF) that is reviewed and approved by the Ethics Committee (EC) / Institutional Review Board (IRB) for the site.
2. Subject agrees to comply with the protocol-mandated follow-up procedures and visits.
3. The subject is a male or non-pregnant female * 18 years old with an expected lifespan sufficient to allow for completion of all study procedures. Female subjects of childbearing potential must have a negative pregnancy test (urine or blood) within 14 days prior to the index procedure.
4. The subject has symptomatic (non-malignant) venous outflow obstruction in iliofemoral *venous segments* (unilateral obstruction of the common femoral vein, external iliac vein, common iliac vein, or any combination thereof) of * 50% as determined by catheter contrast venography.
5. The subject has symptomatic venous outflow obstruction (non-malignant) in iliofemoral venous segments with a Clinical-Etiology-Anatomic-Pathophysiologic Score CEAP *C* * 3 or a Venous Clinical Severity Score VCSS pain score of * 2.
6. The subject is able and willing to comply with any required medication regimen.
7. The reference vessel diameter(s) (RVD) is (are) between 7mm and 19mm as determined by the Investigator*s visual estimate.

Exclusion criteria

1. The subject is unable or unwilling to provide written informed consent, or is unable or unwilling to conform to the study protocol follow-up procedures and visits. ;2. The subject is or plans to become pregnant during the study.
3. The subject has contralateral disease of the common femoral vein, external iliac vein, common iliac vein, or any combination thereof and does not meet the venous outflow obstruction requirement as determined by the treating Investigator or the target vessel has a malignant obstruction.
4. The subject is asymptomatic, has a CEAP *C* <3, or a VCSS pain score of <2.
5. The subject has a venous obstruction that extends into the inferior vena cava (IVC) or below the level of the lesser trochanter.
6. The subject has a known uncorrectable bleeding diathesis or active coagulopathy.
7. The subject has a known allergy or sensitivity to Nickel or Titanium or has intolerance to antiplatelet, anticoagulant or thrombolytic medications required per the protocol
8. The subject has a known allergy or sensitivity to contrast media, which cannot be adequately pre-medicated.
9. The subject has any planned surgical interventions (other than pre-stenting procedures of thrombolysis, thrombectomy, and/or vena cava

filter placement in patients at high risk for pulmonary embolism) within 30 days prior to, or within 30 days after the planned study procedure.
10.The subject has a lesion(s) or occlusion(s) which cannot be traversed with a guidewire.
11.The subject has had prior stenting in the target vessel.
12.The subject has iliofemoral venous segments unsuitable for treatment with available sizes of study devices.
13.The subject has another medical condition, which, in the opinion of the Investigator, may cause him/her to be non-compliant with the protocol, confound the data interpretation, or is associated with a life expectancy insufficient to allow for the completion of study procedures and follow-up.
14.The subject is currently participating in an investigational drug, biologic, or another device study for which the investigational treatment has not ended. Studies requiring extended follow-up for products that are now commercially available are not considered investigational studies.
15.The subject is currently on dialysis or has a serum creatinine * 2.5 mg/dl.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-01-2017
Enrollment:	34
Type:	Actual

Medical products/devices used

Generic name:	Venovo venous stent

Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	17-10-2016
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	28-02-2018
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	27-06-2018
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	04-12-2019
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NCT02655887
CCMO	NL56904.068.16