Post-Approval Study of the GORE® VIABAHN® Endoprosthesis for Treatment of In-Stent Restenosis in the Superficial Femoral Artery.

Published: 16-06-2016
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To evaluate the post-market performance of the GORE® VIABAHN® Endoprosthesis for the treatment of in-stent restenosis in the superficial femoral artery.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Vascular disorders NEC
Study type	Interventional

Summary

ID

NL-OMON43750

Source
ToetsingOnline

Brief title
ISR study

Condition

- Vascular disorders NEC

Synonym
artherosclerotic stenosis, peripheral (arterial) disease

Research involving
Human

Sponsors and support

Primary sponsor: W. L. Gore & Associates Inc, U.S.A.
Source(s) of monetary or material Support: W.L. Gore & Associates

Intervention

Keyword: endoprosthesis, in-stent restenosis

Outcome measures

Primary outcome

Effectiveness Endpoint: Primary patency at 12 months by Kaplan-Meier analysis

Safety Endpoint: Device- and procedure-related serious adverse events (SAE) within 30 days of the procedure.

Secondary outcome

The secondary endpoints for this study include:

Acute Procedural Success

* Primary Patency at 30 days, 12, 24, & 36 months

* Primary Assisted Patency at 30 days, 12, 24, & 36 months

* Secondary Patency at 30 days, 12, 24, & 36 months

* Freedom from TLR at 30 days, 12, 24, & 36 months

* Freedom from Major Amputation at 30 days, 12, 24, & 36 months

* Change in Ankle-Brachial Index from pre-procedure at 30 days, 12, 24, & 36 months

* Change in Rutherford Category from pre-procedure at 30 days, 12, 24, & 36 months

* Stent Fracture Assessment at 12, 24, & 36 months

Study description

Background summary

The following treatment modalities have been used globally to treat in-stent restenosis (ISR) of the superficial femoral artery (SFA):
• Conventional percutaneous transluminal angioplasty (PTA)
• Cutting balloon
• Cryoplasty
• Atherectomy
• Re-stenting
• Drug covered balloons
• Drug-eluting stents

The GORE® VIABAHN® Endoprosthesis has been utilized as a treatment option for SFA ISR. The flexibility of the VIABAHN® Endoprosthesis, as exemplified by its low rate of fracture in long lesion lengths, allows it to withstand the mechanical forces of the SFA10. Additionally, the ePTFE (expanded polytetrafluoroethylene) can provide a physical barrier between the arterial lumen and in-growth from neointimal formation. Since this has been hypothesized to be the failure mechanism of the original stent, it would stand to reason that blocking further neointimal ingrowth via an ePTFE covering would provide a promising treatment strategy.

Study objective

To evaluate the post-market performance of the GORE® VIABAHN® Endoprosthesis for the treatment of in-stent restenosis in the superficial femoral artery.

Study design

This study is a prospective, multicenter, non-randomized single-arm study.

Intervention

Angiographic confirmation of final eligibility, Deployment of study device, Post-procedural angiography, Adverse Event.

Study burden and risks

The study procedures are described in section 5 of the protocol, pages 10-15.
In summary:
Screening: Informed consent, medical history, demographics
Treatment: Angiographic confirmation of final eligibility, deployment of study device, post-procedural angiography, adverse events
Follow-up Schedule: 30 days, 12, 24 and 36 months
Follow-up Assessments: Adverse events, ABI, Rutherford, X-ray (12, 24, 36 months), duplex ultrasound

The risks associated with the GORE® VIABAHN® Endoprosthesis for use in in-stent

restenosis are expected to be similar to the risks associated with the use of PTA or other endovascular procedures in the superficial femoral artery.

Such risks associated with these devices, including the GORE® VIABAHN® Endoprosthesis include, but are not limited to:
• Hematoma
• Stenosis
• Thrombosis or occlusion
• Distal embolism
• Side branch occlusion
• Vessel wall trauma and/or rupture
• False aneurysm
• Infection
• Inflammation
• Fever and/or pain in the absence of infection
• Deployment failure
• Malposition
• Malapposition
• Device migration
• Device failure
Risks associated with endovascular procedures include, but are not limited to:
• Access site infection
• Entry site bleeding and/or hematoma
• Vessel thrombosis
• Occlusion
• Psuedoaneurysm
• Trauma to the vessel wall including perforation, rupture, or dissection
• Distal embolization
• Arteriovenous fistula formation
• Transient or permanent contrast induced renal failure
• Renal toxicity
• Sepsis or shock
• Radiation injury
• Myocardial infarction
• Fever
• Pain
• Inflammation
• Death

The GORE® VIABAHN® Endoprosthesis should not be used in patients with known hypersensitivity to heparin, including those patients who have had a previous incidence of Heparin-Induced Thrombocytopenia (HIT) type II.

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

Potential subjects must meet all of the following clinical inclusion criteria:
1. Patient is >= 18 years old at the time of informed consent signature
2. Patient is willing to give written informed consent
3. Patient has a previously implanted (>30 days) non-covered stent(s) located in the superficial femoral artery
4. Patient has life-style limiting claudication, resting leg pain or minor tissue loss (Rutherford category 2-5)
5. Patient demonstrates an ABI <= 0.9. If ABI > 0.9 or not measureable, patient is eligible for study if toe-brachial index (TBI) is <= 0.5
6. Patient is male, infertile female or female of childbearing potential with a negative beta human chorionic gonadotrophin (hCG) pregnancy test within 7 days of the index procedure
7. Patient is capable of complying with protocol requirements, including follow-up

visits;Potential subjects must meet all of the following angiographic inclusion criteria:
1. Patient has >= 50% in-stent restenosis and/or an occlusion in a previously implanted (>30 days) non-covered stent(s) located in the superficial femoral artery defined as beginning at least 1 cm below the origin of the profunda femoris artery and ending at least 1 cm above the intercondylar notch
2. Patient has a maximum total lesion length of 270 mm, consisting of in-stent and adjacent occlusive disease
3. Patient has a minimum of 1 cm of non-stenosed vessel both proximal and distal to the target lesion(s)
4. Patient has a reference vessel diameter between 4.0 and 6.5 mm
5. The guidewire and delivery system must cross the target lesion(s) intraluminally
6. Patient has a patent popliteal artery (<50% stenosis) distal to the target vessel
7. Patient has at least 1 patent infrapopliteal runoff vessel (<50% stenosis) not requiring intervention
8. Angioplasty balloon can be fully expanded in the target lesion during pre-treatment step

Exclusion criteria

Potential subjects will not be eligible for study participation if they meet any of the following clinical exclusion criteria:
1. Patient has a known allergy to stent graft components (nickel-titanium or ePTFE)
2. Patient has known allergy to contrast media that cannot be adequately pre-medicated prior to the study procedure
3. Patient with known hypersensitivity to heparin, including those patients who have had a previous incidence of heparin-induced thrombocytopenia (HIT) type II
4. Patient has a known intolerance to anticoagulation or antiplatelet therapy
5. Patient has an uncorrected bleeding disorder (platelet count <80,000/µL)
6. Patient has any known coagulation disorder, including hypercoagulability
7. Patient has severe chronic renal insufficiency (creatinine level >= 2.5mg/dL) within 30 days prior to study procedure unless currently on hemodialysis
8. Patient has septicemia or uncontrolled infection
9. Patient has any planned surgical intervention/procedure within 30 days of the study procedure
10. Patient has major distal amputation (above the transmetatarsals) in the study or non-study limb
11. Patient has prior ipsilateral femoral artery bypass
12. Patient has severe medical comorbidities (untreated coronary artery disease (CAD)/congestive heart failure (CHF), severe chronic obstructive pulmonary disease (COPD), metastatic malignancy, dementia, etc) or other medical condition that would preclude compliance with the study protocol or 3-year life expectancy
13. Patient has severe ipsilateral common or deep femoral disease requiring intervention
14. Patient has any previous surgery in the target vessel
15. Patient has had vascular access via the lower extremities within 30 days of the index procedure
16. Patient has had previous target vessel in-stent restenosis treated by relining with another

stent
17. Patient is currently participating in another clinical research trial, unless approved by Sponsor;Potential subjects will not be eligible for study participation if they meet any of the following angiographic exclusion criteria:
1. Patient has untreated flow-limiting aortoiliac stenotic disease
2. Patient has an aneurysm adjacent to the target lesion(s)
3. Patient has perioperative unsuccessful ipsilateral percutaneous vascular procedure to treat inflow prior to enrollment during the index study procedure
4. Patient has femoral or popliteal aneurysm located in the target vessel
5. Patient has non-atherosclerotic disease resulting in occlusion (e.g. embolism, Buerger*s disease, vasculitis)
6. Patient has angiographic evidence of intra-arterial thrombus or atheroembolism from inflow treatment
7. Patient has target lesion access not performed by transfemoral approach

Study design

Design

Study phase:	4
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-04-2017
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	GORE® VIABAHN® Endoprosthesis
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	16-06-2016
Application type:	First submission
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	NCT02542267
CCMO	NL54621.091.15