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GORE VIABAHN® endoprosthesis with bioactive propaten surface versus bare nitinol stent in the treatment of TASC B, C and D lesions in superficial femoral artery occlusive disease

Submission date 18/01/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 07/05/2009	**Overall study status** Completed	
Last Edited 12/10/2015	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Study information

Scientific Title
GORE VIABAHN® endoprosthesis with bioactive propaten surface versus bare nitinol stent in the treatment of TASC B, C and D lesions in superficial femoral artery occlusive disease

Acronym
VIASTAR

Study objectives
In comparison to the use of bare nitinol stents in treating chronic long Superficial Femoral Artery (SFA) lesions, the use of the GORE VIABAHN® endoprosthesis with bioactive propaten surface will result in greater mid- and long-term patency of the treated arterial lesion.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Medical University of Vienna approved on the 26th September 2007 (ref: EK Nr 203/2007)

Primary study design
Interventional

Study design
Randomised controlled multicentre trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Peripheral arterial occlusive disease

Interventions
Percutaneous transluminal stenting with GORE VIABAHN® endoprosthesis with Propaten bioactive surface vs bare nitinol stent"

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Efficacy: Primary patency based on color doppler ultrasonography (CDUS) and computed tomographic angiography (CTA) at 1 year post-procedure
2. Safety: Composite of major procedural (30-day) adverse events

Key secondary outcome(s)
1. Primary assisted patency. Timepoints: 12 and 24 months.
2. Secondary patency. Timepoints: 12 and 24 months.
3. Technical success. Timepoints: Immediately after intervention.
4. Target vessel revascularisation. Timepoints: 12 and 24 months.
5. Target lesion revascularisation. Timepoints: 12 and 24 months.
6. Clinical success. Timepoints: 1 month, 6, 12 and 24 months.
7. Primary composite safety and efficacy endpoint. Timepoints: 1 month and 12 months.

8. Change in ankle-brachial index (ABI). Timepoints: 1, 6, 12 and 24 months.
9. Alternate Peak Systolic Velocity Ratios (PSVR of 2.5 or less). Timepoints: 1, 6, 12 and 24 months.

Completion date
01/04/2012

Eligibility

Key inclusion criteria
1. Lifestyle-limiting claudication or rest pain (meeting angiographic entry criteria) affecting a lower extremity (Fontaine stages II-IV)
2. Subject (or their legal guardian) has read, understood and provided written informed consent, which has been reviewed and approved by the Institutional Review Board
3. At least 18 years of age
4. Noninvasive lower extremity arterial studies within 45-days prior to study procedure demonstrating resting Ankle-Brachial Index (ABI) ? 0.8 in the study limb
5. If applicable, staged ipsilateral vascular procedure = 14 days prior to study procedure. ABIs must be completed prior to the study procedure a minimum of 14 days after the staged vascular procedure
6. If applicable, vascular treatment on non-study leg for bilateral claudication = 14 days prior to study procedure demonstrating Fontaine stage I in non-study leg at the time of study procedure. ABIs must be completed prior to the study procedure a minimum of 14-days after treatment on the non-study leg
7. Male, infertile female, or female of child bearing potential practicing an acceptable method of birth control with a negative pregnancy test within 7 days prior to study procedure
8. Projected life expectancy of greater than three years
9. The ability to comply with protocol follow-up requirements and required testing
10. Angiographic and Lesion Requirements (assessed intraoperatively):
a. Multiple stenoses or occlusions totalling >15 cm with or without heavy calcification or recurrent stenoses or occlusions that need treatment after two endovascular interventions (>50% by visual estimate) located in the region beginning 1 cm below origin of the profunda femoris artery and ending 5 cm above the radiographic knee joint. Prior angioplasty, if applicable on the target lesion, must have been performed = 6 months prior to the study procedure
b. Orifice and proximal 1 cm of SFA are patent
c. Popliteal artery is patent 5 cm proximal to the radiographic knee joint line
d. Reference diameter of 4.07.5 mm in proximal and distal treatment segments within the SFA
e. Angiographic evidence of a minimum of at least one tibial artery runoff to the ankle that does not require intervention
f. Guidewire has successfully traversed lesion and is within the true lumen of the distal vessel

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit

18 Years

Sex
All

Key exclusion criteria
1. Untreated flow-limiting aortoiliac occlusive disease
2. Any previous stenting or surgery in the target vessel
3. Subjects with arterial lesions requiring treatment with device diameters other than 5, 6, 7, or 8 mm
4. Severe ipsilateral common femoral/profunda disease requiring surgical intervention
5. Femoral or popliteal aneurysm
6. Non-atherosclerotic disease resulting in occlusion (e.g., embolism, Buergers disease, vasculitis)
7. Tibial artery disease requiring treatment
8. Prior ipsilateral femoral artery bypass
9. 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 post-procedural ambulation
10. Popliteal artery vascular access at any time during procedure
11. Serum creatinine >2.5 mg/dL within 45 days prior to study procedure
12. Major distal amputation (above the transmetatarsal) in the study or non-study limb
13. Septicemia
14. Any previously known coagulation disorder, including hypercoagulability
15. Morbid obesity or operative scarring that precludes percutaneous approach (physician's discretion)
16. Contraindication to anticoagulation or antiplatelet therapy
17. Known allergies to stent/stent-graft components
18. History of prior life-threatening reaction to contrast agent
19. Currently participating in another clinical research trial

Date of first enrolment
01/04/2009

Date of final enrolment
01/04/2012

Locations

Countries of recruitment
Austria

Germany

Study participating centre
Medical University of Vienna
Vienna
Austria
1090

Sponsor information

Organisation
Medical University of Vienna (Austria)

ROR
https://ror.org/05n3x4p02

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Medical University of Vienna (Austria)

Funder Name
Vienna General Hospital (Austria)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	08/10/2013		Yes	No
Results article	results	01/02/2015		Yes	No