The GORE VBX FORWARD Clinical Study: A Comparison of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis to Bare Metal Stenting for Patients with Complex Iliac Occlusive Disease

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The primary objective of this trial is to demonstrate the superiority of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis for primary patency when compared to bare metal stenting for the treatment of patients with complex iliac occlusive...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Arteriosclerosis, stenosis, vascular insufficiency and necrosis
Study type	Observational invasive

Summary

ID

NL-OMON55893

Source
ToetsingOnline

Brief title
FORWARD study

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
peripheral artery disease / narrowing arteries

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Bare Metal Stent, Peripheral Artery Disease, VBX Device

Outcome measures

Primary outcome

Primary Patency through 1 year

Secondary outcome

1. Technical success at final angiography

2. Acute procedural success through vascular closure

3. Clinical success through 1 month

4. Hemodynamic status through 5 years

5. Change in EQ-5D-5L through 5 years

6. Change in WIQ through 5 years

7. Primary patency through 5 years

8. Freedom from binary restenosis through 5 years

9. Primary assisted patency through 5 years

10. Secondary patency through 5 years

11. Freedom from target lesion revascularization through 5 years

12. Cumulative reintervention rate through 5 years

13. Freedom from clinically driven target lesion revascularization through 5

years

14. Amputation-free survival through 5 years

15. Survival through 5 years

16. Change in Rutherford Category through 5 years

Study description

Background summary

The GORE VBX FORWARD Clinical Study is prospective, multicenter, randomized-controlled, Post-Marketing clinical study of a CE Marked Medical Device- The GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis (VBX Stent Graft).

With reduced blood flow in the iliac arteries and they may be partially or entirely obstructed, typically by atherosclerotic plaques, also called Peripheral Arterial Disease. The reduced blood flow is causing symptoms such as pain and this may cause leg pain when walking (claudication) and other symptoms.
In order to restore the blood flow through arteries, the Study Doctor needs to implant a stent (tiny tube) in the diseased artery in order to keep the vessel open.

The first device, the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis (VBX Device) received initial CE marking in August 2017 and is used to treat Peripheral Artery Disease "Study Device" manufactured by sponsor.
The second device is called a Bare Metal Stent (BMS) the *Control Device*. This type of device is manufactured by other companies and is approved (CE marking) to treat Peripheral Artery Disease.
This research study will look at how effective the Study Device is compared to Control Device and how it works for Peripheral Artery Disease from the procedure up to 5 years. To collect clinical data about safety and performance of the medical devices after the implant and throughout the device functional lifetime.

Study objective

The primary objective of this trial is to demonstrate the superiority of the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis for primary patency when compared to bare metal stenting for the treatment of patients with complex iliac occlusive disease.

Study design

Prospective, multicenter, randomized, controlled clinical trial.

Study burden and risks

Subject*s participation in this study will last 5 years and consists of a screening period, procedure and discharge and a follow-up period. During the FU period, subjects will need to visit the study site 7 FU visits. Participants will be subjected to additional ABI test.

Unanticipated risks may occur, there are possible risks and inconveniences involved when participating in any research study.

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

• Patient has symptomatic claudication or rest pain, or minor tissue loss (Rutherford Categories 2-5)
• Patient has de novo or restenotic lesion(s) found in the common and/or external iliac artery(ies)
• Patient has: Unilateral or bilateral single or multiple lesions (>50% stenosis or chronic total occlusion) each between 4 and 11 cm in length
• Patient has a target vessel diameter visually estimated to be approximately between 5 mm and 13 mm
• Patient has a sufficient (<50% stenotic) common femoral artery and at least one sufficient (<50% stenotic) femoral artery (deep or superficial).
• Patient has at least one sufficient (<50% stenotic) infrapopliteal run-off vessel.

Exclusion criteria

• Patient has a lesion requiring drug-coated balloon angioplasty, atherectomy, lithotripsy, or any ablative device to facilitate stent delivery
• Patient has an abdominal aortic artery occlusion or aneurysm
• Patient has isolated common iliac artery stenosis that can be treated with a single device (i.e., common iliac artery stenosis that does not require kissing stents or extended into the external iliac artery).
• Patient has outflow disease that requires concomitant interventions (i.e., common femoral endarterectomy or femoral / tibial revascularization)

Study design

Design

Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-03-2024

Enrollment:	20
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	23-10-2023
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	20-02-2024
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	NCT05811364
CCMO	NL84685.091.23