

Prospective, Non-Randomised Clinical Trial to investigate the BeGraft Aortic Stent Graft System and the BeGraft Peripheral Stent Graft System treating Aorto-iliac Occlusive Disease with CERAB (Covered Endovascular Reconstruction of Aortic Bifurcation)

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The objective of this clinical investigation is to evaluate the safety and performance of the BeGraft Aortic covered stent Graft System & the BeGraft Peripheral covered stent Graft System (Bentley Innomed, Hechingen, Germany) in CERAB...

Ethical review

Approved WMO

Status

Recruitment started

Health condition type

Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Study type

Interventional research previously applied in human subjects

Summary

ID

NL-OMON56642

Source

ToetsingOnline

Brief title

CERAB

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym

aorto-iliac occlusive disease blockage of iliac and aortic arteries

Research involving

Human

Sponsors and support

Primary sponsor: FCRE - Foundation for Cardiovascular Research and Education

Source(s) of monetary or material Support: Bentley InnoMed GmbH

Intervention

- Medical device

Keyword: Aorto-iliac occlusive disease, BeGraft Aortic Stent Graft System, BeGraft Peripheral Stent Graft System, CERAB

Explanation

N.a.

Outcome measures

Primary outcome

<p>Primary performance Endpoint:

1. Freedom from clinically-driven target lesion revascularization (CD-TLR) at
12 months, defined as freedom from repeat endovascular revascularization to
maintain or re-establish patency within the treated lesion.

Primary Safety Endpoint:

1. Incidence of Serious Adverse Device Effects (SADE) and procedure related
Serious Adverse Events (SAE) at 12 months follow up. </p>

Secondary outcome

<p>Secondary Performance Endpoints: 1. Technical success rate after procedure
defined as successful introduction and deployment of the study devices BeGraft
Aortic covered stent Graft System & the BeGraft Peripheral covered stent Graft
System (Bentley Innomed, Hechingen, Germany) for CERAB procedures 2. Freedom
for conversion to open surgical repair of the target lesion. 3. Patency rate of
the target vessel (primary, primary assisted and secondary). 4. Time to
re-vascularization/re-intervention. 5. Patient reported outcomes at 30 days
post-procedure, 6-, 12-, and 24-months compared to pre-procedure: a. Walking
Impairment Questionnaire (WIQ) b. Quality of Life Questionnaire (EQ-5D) 6.
Clinical success at every follow up visit, defined as an improvement of
Rutherford classification of one class or more compared to the pre-procedure
Rutherford classification. 7. Hemodynamic improvement defined as increase in
Ankle Brachial Index (ABI) of at least 0.10 compared to baseline ABI

(pre-procedure) at 30 days post-procedure, 6-, 12-, and 24-months. Secondary
Safety Endpoints: 1. Incidence of Serious Adverse Device Effects (SADE) and
procedure related Serious Adverse Events (SAE) at 1-, 6- and 24-months after
the procedure. 2. 30-day mortality. 3. Overall survival rate at up to 30-days
post-procedure, 6-, 12- and 24-months. 4. Incidence of Major Adverse Events
(MAE) at up to 30-days post-procedure, 6-, 12- and 24-months.

Study description

Background summary

Peripheral Arterial Disease (PAD) affects more than 200 million people worldwide and is the leading cause of lower limb amputation . Aorto-iliac atherosclerosis is common in patients with symptomatic PAD and therefore aorto-iliac interventions, either surgical or endovascular, are often performed in this patient population.

The CERAB technique was designed to achieve an improved anatomical and physiological reconstruction of the aorto-iliac segment. The aim of the procedure is to improve the results of endovascular reconstruction of this anatomical region, especially in patients with occlusive and/or very calcified atherosclerotic disease. First trials demonstrated that the CERAB technique is a safe and feasible technique for the treatment of extensive aorto-iliac occlusive disease (AIOD) with satisfying patency and clinical improvement, especially in patients treated for TASC II D lesions.

Endovascular repair offers several benefits over conventional surgery, namely a less invasive approach, faster recovery, lower morbidity, lower early post-operative mortality and a lower rate of perioperative complications.

However, more long-term follow ups are required to confirm these promising results

The hypothesis of the planned work is the safe implantation of the BeGraft Peripheral Stent Graft System and BeGraft Aortic covered stent Graft system in CERAB configuration for Aorto-iliac Occlusive Disease.

Study objective

The objective of this clinical investigation is to evaluate the safety and performance of the BeGraft Aortic covered stent Graft System & the BeGraft Peripheral covered stent Graft System (Bentley Innomed, Hechingen, Germany) in CERAB configuration (Covered Endovascular Reconstruction of Aortic Bifurcation)

for Aorto-iliac Occlusive Disease.

Study design

This investigational trial, will be performed to show success of the implantation and to collect the data about clinical performance as well as potential unknown side effects, when BGA and BGP are used in the CERAB configuration

A prospective, non-randomized, multi-center design is used to ensure a representative sample of the physicians who have performed the procedure and to provide a reasonable enrolment period for the required data to be collected.

Intervention

The procedure is an endovascular procedure that takes place in an angiochamber after local or regional anesthesia, the aorto-iliac lesion will be reached through the femoral arteries. An arterial sheath is introduced and guided to the aortoiliac occluded lesion. According to the local standard of care, the lesion is crossed with the guide wire. Once this has happened, the BeGraft Aortic Stent Graft System will be guided to the lesion via this guide wire and opened. Once the aortic stent is in place, a balloon is introduced and the stent opens maximally. Next, 2 BeGraft Peripheral Stent Graft Systems are placed distal to the BeGraft Aortic Stent Graft in the distal aorta and common iliac aorta. Both stents are maximally opened using a balloon.

Study burden and risks

The patients eligible for the CERAB study are patients with a lesion in the aorto-iliac arteries and are in need of treatment anyway. Regardless of their participation in the study, they should undergo an endovascular procedure and attend follow-up visits. The investigational devices used in this study have a CE mark, but for a different indication than those treated in this study. For the screening and follow-up visits, the examinations are by general standard, except for the questionnaires: walking impairment questionnaire, EQ-5D-5L questionnaire. The risks associated with the procedure are similar to those associated with standard endovascular procedures. The details are described in the protocol of the study.

Contacts

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Public

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Trial sites

Trial sites in the Netherlands

Noordwest Ziekenhuisgroep

Target size: 10

Haaglanden Medisch Centrum

Target size: 10

Zuyderland Medical Center

Target size: 10

Universitair Medisch Centrum Groningen

Target size: 10

Maastricht Universitair Medisch Centrum +

Target size: 10

Martini Ziekenhuis

Target size: 10

Rijnstate Ziekenhuis

Target size: 10

Listed location countries

Germany, Netherlands

Eligibility criteria

Age

Elderly (65 years and older)

Adults (18-64 years)

Inclusion criteria

1. Patient has been identified with an chronic aorto-iliac occlusive lesion, with clinical necessity for treatment.
2. The patient has been diagnosed with symptomatic peripheral artery disease, defined by Rutherford Becker Classification score 2 to 5.
3. Patient has a projected life-expectancy of at least 24 months.
4. Patient is ≥ 18 years old.
5. Patient is willing/capable and provides written consent to participate to the trial and confirmed to attend the expected follow-up visits.

Angiographic inclusion criteria:

1. Patient's anatomy is eligible for CERAB treatment, without the need for chimneys and can be treated with a \varnothing 12 mm BGA.
2. The aorto-iliac lesion begins at least 1 cm below the patent renal arteries without a need for treatment.
3. A maximum of 3 BeGraft Peripheral (\varnothing 7 or 8 mm) per limb in the iliac artery can be used. In case a \varnothing 7 mm is used to extend, the overlapping end must be post-dilated to ensure proper flow.
4. The target lesion has angiographic evidence of stenosis $>50\%$ or occlusion.
5. Patient's common femoral artery and deep femoral artery are patent.

Exclusion criteria

1. Patient is currently participating in another interventional drug trial or device trial that has not completed the entire follow up period.
2. Patient has planned any surgical intervention/procedure, that is not related to the study procedure, within 30 days after the study procedure.
3. Patient had a Myocardial infarction or stroke within a period of 3 months prior to the study procedure.
4. Patient had surgery (e.g. bypass surgery or stenting) in target vessels previously.
5. Patient has an acute severe systemic infection at time of screening or in period of 30 days prior to screening.
6. Patient has fresh thrombus at time of screening or in period of 14 days prior to screening.
7. Patient has a CERAB procedure that is staged.
8. Female patient with childbearing potential not taking adequate contraceptives.
9. Patients for whom antiplatelet therapy, anticoagulants or thrombolytic drugs are contraindicated.
10. Patients with known hypersensitivity to the stent material (L605) and/or PTFE.
11. Patients who are placed in an institution due to an institutional or court order.

12. An aneurysm in the abdominal aortic and iliac segments where CERAB will be placed is present.
13. Patient has or had aortic coarctation.
14. Patient had aortic injury/trauma related interventions previously.
15. Patient had suprarenal/visceral segment reconstructions previously.

Angiographic exclusion criteria

1. Failure of recanalization
2. A relevant accessory renal artery (>3 mm) in the infrarenal aorta is present, that might be occluded during the procedure.

Study design

Design

Study phase:	N/A
Study type:	Interventional research previously applied in human subjects
Intervention model:	Single
Allocation:	N/A: single arm study
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL	
Recruitment status:	Recruitment started
Start date (anticipated):	06-08-2024
Enrollment:	70
Duration:	24 months (per patient)
Type:	Actual
WORLD	
Recruitment status:	Recruitment started
Start date (anticipated):	21-03-2024
Enrollment:	109
Type:	Actual

Medical products/devices used

Product type:	Medical device
Generic name:	BeGraft Peripheral Stent Graft System/BeGraft Aortic StentGraft System
Registration:	Yes - CE outside intended use

IPD sharing statement

Plan to share IPD: Undecided

Plan description

N.a.

Ethics review

Approved WMO	
Date:	18-03-2024
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	04-12-2024
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	27-05-2025
Application type:	Amendment
Review commission:	METC Oost-Nederland

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
CCMO	NCT05805111
CCMO	NL83883.000.23
Research portal	NL-007053