# 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…

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Arteriosclerosis, stenosis, vascular insufficiency and necrosis |
| **Study type** | Interventional |

## 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

## Intervention

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

## Outcome measures

### Primary outcome

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.

### Secondary outcome

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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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

### 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 Ø 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 (Ø 7 or 8 mm) per limb in the iliac artery can be used. In case a Ø 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 type:** Interventional

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

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 06-08-2024 |
| Enrollment: | 60 |
| Type: | Actual |

## Medical products/devices used

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|---|---|
| Generic name: | BeGraft Peripheral Stent Graft System/BeGraft Aortic Stent Graft System |
| Registration: | Yes - CE outside intended use |

# Ethics review

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| 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)

# 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 | NCT05805111 |
| CCMO | NL83883.000.23 |