Covered endovascular reconstruction of aortic bifurcation (CERAB) for extensive aortoiliac occlusive disease

Published: 07-03-2019
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Objective of the study is to evaluate the performance of the CERAB configuration using Bentley covered stents.

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

Summary

ID

NL-OMON48644

Source
ToetsingOnline

Brief title
CERAB-trial

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
Narrowing vascular disease

Research involving
Human

Sponsors and support

Primary sponsor: Rijnstate Ziekenhuis
Source(s) of monetary or material Support: Bentley Innomed

Intervention

Keyword: aorta bifurcation, CERAB, occlusive disease

Outcome measures

Primary outcome

- Technical success is defined as successful implantation of the CERAB device without occlusion during the first 30-days after implantation and without conversion to open repair

- Primary patency at 12 months

Secondary outcome

Technical:

* Patency rates

* Target vessel revascularization rate

* Conversion to open surgery

Clinical:

* Freedom from Reinterventions

* 30-day morbidity

* Incidence of serious adverse events device or procedural related within the 3, 6 and 12 months post intervention period

* Overall and reintervention-free survival

* Clinical improvement, as measured by the Rutherford category

*Patient reported outcomes including general health status, Quality of life and disease specific outcomes

Study description

Background summary

Endovascular treatment is rapidly taking over surgery for aorto-iliac occlusive disease (AOID), also in extensive pathology. This is related to its minimally invasiveness, decreasing the procedural morbidity rate. When the aortic bifurcation was involved in the lesion, the patency rates of kissing stents configurations were often inferior to open repair. In 2013 the Covered Endovascular Reconstruction of the Aortic Bifurcation (CERAB) technique was introduced in an attempt to improve endovascular treatment results by a more anatomical and physiological reconstruction, with a subsequent improved clinical outcome.

Study objective

Objective of the study is to evaluate the performance of the CERAB configuration using Bentley covered stents.

Study design

This is a real world, multicenter, prospective investigator initiated trial to get a further insight on the efficacy of the CERAB procedure for extensive aortoiliac occlusive disease.

Intervention

CERAB-technique, as described in the introduction of the study protocol.

Study burden and risks

Risk assessment can be found in chapter 14.1 of the study protocol.

Contacts

Public
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NL
Scientific

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NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Age 18 years or older
- Provided written informed consent
- Clinical necessity for treatment
- Eligible anatomy for CERAB without the need for chimney*s
- TASC-2 classification as assigned in the study protocol

Exclusion criteria

- Patient is participating in another conflicting clinical study
- Patient*s life expectancy <2 years as judged by the investigator
- Patient has a psychiatric or other condition that may interfere with the study
- Patient has a known allergy to any device component
- Patients with a systemic infection who may be at increased risk of endovascular graft infection.
- Patient has a coagulopathy or uncontrolled bleeding disorder
- Patient had a CVA or an MI within the prior three months
- Patient is pregnant (Female patients of childbearing potential only)

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-05-2019
Enrollment:	35
Type:	Actual

Medical products/devices used

Generic name:	CERAB-stent
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	07-03-2019
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	27-03-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	27-05-2019
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
CCMO	NL65682.091.18