A randomized controlled trial evaluating the safety and efficacy of the endovascular treatment of subjects with stenotic or restenotic lesions of the common femoral artery with the Supera Vascular Mimetic Implant compared to surgical Common Femoral Artery Endarterectomy

Published: 20-04-2021
Last updated: 08-04-2024

The objective of this study is to evaluate the 12-month outcomes of stenting with the Supera Peripheral Stent System (Abbott Vascular) versus endarterectomy in symptomatic (Rutherford 2-4) atherosclerotic lesions in the common femoral artery (CFA) (...

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

Summary

ID

NL-OMON55275

Source
ToetsingOnline

Brief title
SUPERSURG RCT

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
peripheral arterial disease, stenosis or re-stenosis of the common femoral artery

Research involving
Human

Sponsors and support

Primary sponsor: ID3 Medical
Source(s) of monetary or material Support: industry Abbott Vascular provided funding to sponsor of the research study

Intervention

Keyword: endovascular treatment, Supera Vascular Mimetic Implant, surgical endarterectomy

Outcome measures

Primary outcome

1. Primary efficacy endpoint at 12 months

To demonstrate the non-inferior efficacy in the group treated with the Supera stent compared to the group treated with endarterectomy for the treatment of atherosclerosis in the common femoral artery (CFA). Efficacy is defined as primary patency: a composite of freedom from clinically-driven target lesion revascularization (CD-TLR) and binary restenosis (restenosis defined as duplex ultrasound (DUS) peak systolic velocity ratio (PSVR) >=2.4 or >=50% stenosis as assessed by an independent DUS core lab in CFA) through 12 months post-index procedure.

2. Primary safety endpoint at 30 days post-index procedure

To demonstrate superior safety in the group treated with the Supera stent compared to the endarterectomy group for the treatment of atherosclerosis in

the CFA. Safety is defined as a composite of overall death, cardiac, pulmonary, renal complications, sepsis, target lesion revascularization (TLR) and wound-related complications (haematoma, seroma, lymphocele, lymphatic leaks with lymphatic fistula, surgical site infections (SSIs) (Szilagyi grade I, II and III)).

Secondary outcome

• Technical success

Supera group: Defined as the ability to cross and stent the lesion to achieve residual angiographic stenosis no greater than 30%.

Endarterectomy group: defined as the ability to remove the atherosclerotic plaque with or without patch (interposition grafts are not allowed). In the imaging subcohort the endarterectomy is considered successful when a residual stenosis no greater than 30% per visual estimation is confirmed.

• Primary patency in the deep femoral artery (DFA), post-index procedure and at 6-, 12-, 24- and 36-months post-index procedure

Primary patency in the DFA is defined as freedom from an occlusion in the DFA as assessed by PSV-values. This PSV-value will be assessed pre-procedure, post-procedure, 6 months and 12 months post-index procedure. At 12 months, the PSV-value will be core-lab controlled.

• Primary patency at 6, 24 and 36 months

Primary patency is a composite of freedom from clinically-driven target lesion revascularization (CD-TLR) and binary restenosis (restenosis defined as duplex

ultrasound (DUS) peak systolic velocity ratio (PSVR) >=2.4 or >=50% stenosis as assessed by DUS in CFA) through 6 months post-index procedure

• TLR at 6-, 12-, 24- and 36-months post-index procedure

TLR is defined as a reintervention to maintain or restore the patency in the target lesion. TLR is clinically-driven (CD) when the TLR was needed due to symptoms or drop of ankle brachial index (ABI) of >=20% or >0.15 when compared to post-procedure

• TVR at 6-, 12-, 24- and 36-months post-index procedure

TVR is defined as a reintervention to maintain or restore the patency in the target vessel. TVR is clinically-driven (CD) when the TVR was needed due to symptoms or drop of ankle brachial index (ABI) of >=20% or >0.15 when compared to post-procedure

• Binary restenosis at 6, 12, 24 and 36 months

Binary restenosis is defined as restenosis confirmed by DUS PSVR >=2.4 or >=50% stenosis as assessed by angiographic and DUS images. At 12 months, the images will be core lab controlled.

• Duration of initial hospitalisation stay

Number of hours/days of the initial hospitalisation stay.

• Sustained clinical improvement at 6-, 12-, 24- and 36-months post-index

procedure

Clinical improvement is defined as freedom from major target limb amputation, TVR, worsening target limb Rutherford class (compared to baseline) and decrease in target limb ankle brachial index (ABI) or toe brachial index (TBI) >=0.15 (compared to baseline)

• Change in Walking Impairment Questionnaire (WIQ) score from baseline to 6, 12, 24 and 36 months

• Change in target limb Rutherford class from baseline to 6, 12, 24 and 36 months

• Change in target limb resting ABI or TBI from baseline to 6, 12, 24 and 36 months

• All cause death at 6, 12, 24 and 36 months

• Thrombosis at the target lesion at 6, 12, 24 and 36 months

Study description

Background summary

Although the open surgery in the CFA territory remains the gold standard treatment at the moment, more and more data conclude that endovascular approaches are safer and as efficient therapeutic modalities. Especially reduction in superficial/deep surgical site infections seems to be a great

advantage, like clearly proven in the first TECCO trial. However, longer term data as well as head to head compared data in a randomized controlled trial are mandatory to support the idea of treatment switch from open to endovascular approach in this challenging common femoral artery area.
This study was set up to meet in this unmet need: the endovascular approach with the Supera Vascular Mimetic implant will be compared with the endarterectomy in a randomized controlled trial in terms of non-inferior efficacy and superior safety.

Study objective

The objective of this study is to evaluate the 12-month outcomes of stenting with the Supera Peripheral Stent System (Abbott Vascular) versus endarterectomy in symptomatic (Rutherford 2-4) atherosclerotic lesions in the common femoral artery (CFA) (Azéma type 2 and 3). This evaluation will be done by means of a direct randomized controlled head-to-head comparison.

Study design

The SUPERSURG study is a prospective, physician-initiated, multi-centre, randomized controlled trial to evaluate the efficacy non-inferiority and the safety superiority of the treatment of atherosclerotic lesions in the common femoral artery with the Supera Peripheral Stent System compared to endarterectomy. Eligible patients will be randomized in a 1:1 ratio to endovascular treatment with the Supera stent or endarterectomy. Patients will be followed for 36 months.
The target lesion must be either de novo or a non-stented restenotic lesions located in the common femoral artery, between 1cm proximal to the origin of the circumflex iliac artery and the proximal (2cm) superficial femoral artery and deep femoral artery (2cm) (Azéma Type 2 and 3)

Intervention

Endovascular treatment with Supera Peripheral Stent System compared to Common femoral artery endarterectomy
The trial will randomize 286 patients who are eligible for the study in a 1:1 manner to treatment with either the Supera stent or endarterectomy.

Study burden and risks

The burden on the subjects is miminal. The interventions are Standard of Care, the frequency of visits ot the clinic are the same as when subject would not participate in the study, the examinations during the study visits are the same as if the subject would not participate in the study except for one additional questionnaire at each study visit. Completion of this questionnaire takes 5-10 minutes.

Please note that post-procedure angiography in a subcohort of 40 subjects will not be performed in The Netherlands.

Contacts

Public
ID3 Medical

Keizer Karellaan 584
Sint-Agatha-Berchem 1082
BE
Scientific
ID3 Medical

Keizer Karellaan 584
Sint-Agatha-Berchem 1082
BE

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Clinical inclusion criteria:
CI1. Patient is >=18 years old
CI2. Patient presenting a score from 2 to 4 following Rutherford classification
CI3. Patient is willing to comply with specified follow-up evaluations at the specified times
CI4. Patient understands the nature of the procedure and provides written informed consent, prior to enrolment in the study
CI5. Patient has a life expectancy of at least 12 months

CI6. Prior to enrolment, the guidewire has crossed the target lesion in the endovascular arm. In the surgical arm, the CFE needs to be performed with primary suture or patch implantation.

Angiographic inclusion criteria
AI1. De novo stenotic or restenotic (post-PTA) lesions (<100%) located in the common femoral artery, suitable for both endovascular therapy and endarterectomy
AI2. Target lesion is located within the native CFA: localized between 1cm proximal to the origin of the circumflex iliac artery and the proximal (2cm) superficial femoral artery and deep femoral artery (2cm) (Azéma type 2 and 3 lesions)
AI3. There is angiographic evidence of a patent deep femoral artery and/or superficial femoral artery
AI4. The target lesion has angiographic evidence of >50% stenosis. Occlusions are not allowed

Exclusion criteria

Clinical exclusion criteria
CE1. Presence of another stent in the target vessel that was placed during a previous procedure
CE2. Previous open surgery in the ipsilateral groin
CE3. Patients contraindicated for antiplatelet therapy, anticoagulants or thrombolytics
CE4. Patients who exhibit persistent acute intraluminal thrombus at the target lesion site
CE5. Patients with known hypersensitivity to nickel-titanium and heparin, including those patients who have had a previous incidence of heparin-induced thrombocytopenia (HIT) type II
CE6. Known allergy to contrast media that cannot be adequately pre-medicated prior to study procedure
CE7. Patients with uncorrected bleeding disorders
CE8. Female patients with child bearing potential not taking adequate contraceptives or currently breastfeeding
CE9. Ipsilateral inflow (aorto-iliac) artery treatment before target lesion treatment with a residual stenosis >30%
CE10. Use of thrombectomy, atherectomy or laser device during procedure
CE11. Any patient considered to be hemodynamically unstable at onset of procedure
CE12. Severe medical comorbidities (untreated CAD/CHF, severe COPD, metastatic malignancy, dementia, etc.) or other medical condition that would prelude non compliance with the study protocol or 1-year life expectancy
CE13. Major distal amputation (above the ankle) in the study limb or non-study limb

Angiographic exclusion criteria
AE1. Target lesion involves an (pseudo-)aneurysm or is adjacent to an (pseudo-)aneurysm (within 5mm)
AE2. Iliac inflow disease requiring treatment, unless the iliac artery disease is successfully treated first during the index procedure. Success is defined as <=30% residual diameter stenosis without death or major complications
AE3. Presence of an aortic, iliac or femoral artificial graft
AE4. Occlusion in the target lesion
AE5. Presence of an interposition graft with/without profunda reimplantation

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-09-2021
Enrollment:	40
Type:	Actual

Medical products/devices used

Generic name:	Supera Peripheral Stent System
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	20-04-2021

Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NCT04349657
CCMO	NL73200.068.20