

# 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

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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) (...)

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Arteriosclerosis, stenosis, vascular insufficiency and necrosis
<b>Study type</b>	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)  $\geq 2.4$  or  $\geq 50\%$  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)  $\geq 2.4$  or  $\geq 50\%$  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  $\geq 20\%$  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  $\geq 20\%$  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  $\geq 2.4$  or  $\geq 50\%$  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)  $\geq 0.15$  (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 minimal. The interventions are Standard of Care, the frequency of visits at 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

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BE

### Scientific

ID3 Medical

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## 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  $\geq 18$  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 preclude 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  $\leq 30\%$  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