A randomized trial comparing the ELUVIA* drug-eluting stent versus bare Metal self-expanding nitINol stEnts in the treatmeNt of superficial femoral and/or proximal popliteal arTeries

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To confirm the superior effectiveness of the ELUVIA Drug-Eluting Vascular Stent System (ELUVIA Stent) for treating Superficial Femoral Artery (SFA) and/or Proximal Popliteal Artery (PPA) lesions up to 210 mm in length when compared against bare...

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

Summary

ID

NL-OMON50509

Source
ToetsingOnline

Brief title
EMINENT

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
Peripheral Arterial Disease/de novo or restenotic Superficial femoral artery - proximal popliteal artery lesion

Research involving
Human

Sponsors and support

Primary sponsor: Boston Scientific International SA
Source(s) of monetary or material Support: Industry

Intervention

Keyword: Drug-eluting stent, lower extrimities, PAD

Outcome measures

Primary outcome

Primary Effectiveness Endpoint

The primary effectiveness endpoint assesses primary patency at 12 months post-procedure. This effectiveness endpoint is designed to demonstrate that the 12-month primary patency for the ELUVIA treatment group is superior to the Self-Expanding Bare Nitinol Stents treatment group.

Primary vessel patency is defined as a binary endpoint and will be determined to be a success when the duplex ultrasound (DUS) Peak Systolic Velocity Ratio (PSVR) is <= 2.4 at the 12-month follow-up visit in the absence of clinically-driven TLR or bypass of the target lesion. All DUS readings will be assessed by an independent core laboratory

Secondary outcome

Health-Economics

- Walking Improvement at 12 months assessed by change in Six Minute Hall Walk (6MHW) / treadmill test from baseline, or preceding any Target Vessel Revascularization

- Walking Improvement at 12 months assessed by change in Walking Impairment

Questionnaire (WIQ) from baseline

- Quality of Life Improvement at 12 months assessed by change in EQ-5D-5L * from baseline, or preceding any Target Vessel Revascularization

- Cost effectiveness of ELUVIA* drug-eluting stent versus bare metal self-expanding nitinol stents

- Rate of Primary and Secondary Sustained Clinical Improvement at 12 months as assessed by changes in Rutherford Classification from baseline

- Rate of Hemodynamic Improvement at 12 months as assessed by changes in Ankle-Brachial Index (ABI) from baseline

- Technical success

- Procedural success

- Major Adverse Event (MAE) rate (and individual components) at each time point, defined as all causes of death, target limb major amputation and/or Target Lesion Revascularization (TLR)

- Survival rate at 4 years and 5 years post-procedure

- Primary Patency and Assisted Primary Patency at 6 months, 12 months, 24 months and 36 months using different DUS PSVRs

- Clinically-driven TLR and clinically-driven Target Vessel Revascularization (TVR) Rate at each time point

- Adverse Event Rates (unanticipated, major, serious, device/procedure-related) at each time point

- Number of Stent Fractures reported at 12 months and 24 months utilizing VIVA definitions

- Distribution of Rutherford Class during follow-up as compared to baseline at

1 month, 6 months, 12 months, 24 months and 36 months

- Walking Improvement at 1 month, 6 months, 24 months and 36 months assessed by change in Walking Impairment Questionnaire (WIQ) from baseline

- Quality of Life Improvement at 1 month, 6 months, 24 months and 36 months assessed by change in EQ-5D-5L* from baseline

- Rate of Primary and Secondary Sustained Clinical Improvement as assessed by changes in Rutherford Classification from baseline at 1 month, 6 months, 24 months and 36 months

- Rate of Hemodynamic Improvement as assessed by changes in Ankle-Brachial Index (ABI) from baseline at 1 month, 6 months, 24 months and 36 months

Study description

Background summary

The ELUVIA stent system is intended to improve the luminal diameter in the treatment of symptomatic de novo or restenotic lesions in the native SFA (superficial femoral artery) and/or PPA (proximal popliteal artery).

The ELUVIA stent is a paclitaxel eluting, self-expanding nitinol stent developed on the same stent and delivery system as the BSC Innova* Vascular Self-Expanding Stent System.

The theoretical basis for improved performance with the use of nitinol stents is due to the unique properties of nitinol such as flexibility, persistent radial force when oversized to a vessel, and ability for crush recovery in these high flexion and torsion force areas in the femoropopliteal arteries. In addition, self-expanding nitinol stents are not as prone to external compression as are balloon-expandable stents. Moreover, due to its smaller arterial diameter and complex nature, the femoropopliteal segment does not respond well to rigid stents. As such, the most flexible nitinol stent is needed to mitigate stent fracture that often occurs in the femoropopliteal arteries.

To supress neointimal growth and to prevent restenosis after stent deployment,

the ELUVIA stent is coated with a pharmaceutical, Paclitaxel.
Studies have shown that paclitaxel inhibits neointimal hyperplasia by disrupting normal microtubule function, thereby inhibiting smooth muscle cell migration, proliferation, and extracellular matrix secretion thus supporting short-term local delivery of paclitaxel for inhibiting restenosis in the SFA.

Study objective

To confirm the superior effectiveness of the ELUVIA Drug-Eluting Vascular Stent System (ELUVIA Stent) for treating Superficial Femoral Artery (SFA) and/or Proximal Popliteal Artery (PPA) lesions up to 210 mm in length when compared against bare metal stents, and collect additional data including health economics data.

Study design

A prospective, multi-center study confirming the superior effectiveness of the ELUVIA stent versus Self-Expanding Bare Nitinol Stents in the treatment of lesions 30-210 mm long located in the femoropopliteal arteries in subjects with symptoms classified as Rutherford categories 2-4.
The study is a 2:1 randomized (ELUVIA vs Self-Expanding Bare Nitinol Stents), controlled, single-blind, superiority trial (RCT). Randomization will be stratified to ensure equal distribution of ELUVIA and Self-Expanding Bare Nitinol Stents in different lesion length subsets.

Intervention

test device:
The ELUVIA Stent is a paclitaxel-eluting, self-expanding nitinol stent developed on the same stent and delivery system as the BSC Innova* Vascular Self-Expanding Stent System.

control device:
Commercially available stents in Europe. Permitted stents are Supera (Abbott), Lifestent (CR Bard), Everflex (Covidien/Medtronic), S.M.A.R.T. Flex (Cordis/Cardinal), S.M.A.R.T. Control (Cordis/Cardinal), Pulsar (Biotronik), COMPLETE SE (Medtronic), Misago (Terumo) or Innova (Boston Scientific) indicated for improving luminal diameter for the treatment of de novo or restenotic symptomatic lesions in native vascular disease of the above-the-knee femoropopliteal arteries.

Study burden and risks

The study will not expose the study subjects to any adjunct invasive or stressful examination as compared to if the subject was treated outside the study according to standard practice. both the 'testdevice' and 'control devie'

are CE-marked (commercially available) and are considered standard of care treatment.

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. Subjects age 18 and older
2. Subject is willing and able to provide consent before any study-specific test or procedure is performed, signs the consent form, and agrees to attend all required follow-up visits
3. Chronic, symptomatic lower limb ischemia defined as Rutherford categories 2, 3 or 4
4. Stenotic, restenotic or occlusive lesion(s) located in the native SFA and/or PPA:

a. Degree of stenosis *70% by visual angiographic assessment
b. Vessel diameter >= 4 and *6 mm
c. Total lesion length (or series of lesions) >= 30 mm and * 210 mm (Note: Lesion segment(s) must be fully covered with one or two overlapping ELUVIA stent(s) or Self Expanding Bare Nitinol stent(s))
d. For occluded lesions (chronic occlusions) requiring use of re-entry device, lesion length <= 180 mm
e. Target lesion located at least three centimeters above the inferior edge of the femur
5. Patent infrapopliteal and popliteal artery, i.e., single vessel runoff or better with at least one of three vessels patent (<50% stenosis) to the ankle or foot with no planned intervention

Exclusion criteria

1. Previously stented target lesion/vessel
2. Target lesion/vessel previously treated with drug-coated balloon <12 months prior to randomization/enrollment
3. Subjects who have undergone prior surgery of the SFA/PPA in the target limb to treat atherosclerotic disease
4. Use of atherectomy, laser or other debulking devices such as Rotarex in the target limb SFA/PPA during the index procedure
5. History of major amputation in the target limb
6. Documented life expectancy less than 24 months due to other medical co-morbid condition(s) that could limit the subject*s ability to participate in the clinical study, limit the subject*s compliance with the follow-up requirements, or impact the scientific integrity of the clinical study
7. Known hypersensitivity or contraindication to contrast dye that, in the opinion of the investigator, cannot be adequately pre-medicated
8. Known hypersensitivity/allergy to the stent system or protocol related therapies (e.g., nitinol, paclitaxel, or structurally related compounds, polymer or individual components, and antiplatelet, anticoagulant, thrombolytic medications)
9. Platelet count <80,000 mm3 or >600,000 mm3 or history of bleeding diathesis
10. Concomitant renal failure with a serum creatinine >2.0 mg/dL
11. Receiving dialysis or immunosuppressant therapy
12. History of myocardial infarction (MI) or stroke/cerebrovascular accident (CVA) within 6 months prior to randomization/enrollment
13. Unstable angina pectoris at the time of randomization/enrollment
14. Pregnant, breast feeding, or plan to become pregnant in the next 5 years
15. Current participation in an investigational drug or device clinical study that has not completed the primary endpoint at the time of randomization/ enrollment or that clinically interferes with the current study endpoints (Note: studies requiring extended follow-up for products that were investigational, but have become commercially available since then are not

considered investigational studies)
16. Septicemia at the time of randomization/enrollment
17. Presence of other hemodynamically significant outflow lesions in the target limb requiring intervention at the time of the index procedure
18. Presence of aneurysm in the target vessel
19. Acute ischemia and/or acute thrombosis of the SFA/PPA prior to randomization/enrollment.
20. Perforated vessel as evidenced by extravasation of contrast media prior to randomization/enrollment.
21. Heavily calcified lesions.
22. As applicable by French law, subject who is a protected individual such as an incompetent adult or incarcerated person.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2017
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	ELUVIA Stent
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	17-03-2017
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	21-04-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	13-10-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	13-07-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	18-05-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	22-04-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

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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	NCT02921230
CCMO	NL59014.098.16