Physician-Initiated PMCF Trial Investigating the Solaris Vascular Stent Graft for the treatment of iliac lesions - SOLARIS Peripheral PMCF Trial

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The objective of this clinical investigation is to evaluate, in a controlled setting, the long-term (up to 12 months) safety and efficacy of the Solaris Vascular Stent Graft (Scitech) in clinical settingswhen used according to the indications of the...

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

Summary

ID

NL-OMON50863

Source
ToetsingOnline

Brief title
SOLARIS PMCF Study

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
peripheral vascular disease in iliac arteries

Research involving
Human

Sponsors and support

Primary sponsor: FCRE - Foundation for Cardiovascular Research and Education

Source(s) of monetary or material Support: FCRE - foundation for Cardiovascular Research and Education,SciTech

Intervention

Keyword: iliac arteries, peripheral arterial disease

Outcome measures

Primary outcome

The primary endpoint of the study is primary patency at 12 months , defined as a target lesion without a hemodynamically significant stenosis on duplex ultrasound (>50%, systolic velocity ratio no greater than 2.4) and without Target Lesion Revascularization (TLR) within 12 months.

Secondary outcome

1.Primary patency rate at 1- and 6-month follow-up. Patients that present without a hemodynamically significant stenosis at the target area on duplex ultrasound (>50%, systolic velocity ratio no greater than 2.4) and without prior TLR are defined as being primary patent at the given follow-up.

2. Stent graft occlusion rate at pre-discharge, 1-, 6- and 12-month follow-up.

3. Ankle Brachial Index (ABI) at 1-, 6- and 12-month follow-up compared with the baseline ABI.

4. Amputation rate at 1-, 6- and 12-month follow-up, defined as any amputation above the knee.

5. Performance success rate at baseline, defined as a composite of:

a. successful in sealing acute perforation or rupture

b. successful in treating aneurysms and fistulae

c. restoration of blood flow

6. In-stent restenosis rate

7. Freedom from Target Lesion Revascularization (TLR), defined as freedom from a repeat intervention to maintain or re-establish patency within the region of the treated arterial vessel plus 5mm proximal and distal to the treated lesion edge.

8. Serious Adverse Events (SAEs), defined according to ISO 14155:2020 as any clinical event that is fatal, life-threatening, or judged to be severe by the investigator; resulted in persistent or significant disability; necessitated surgical or percutaneous intervention; or required prolonged hospitalization.

9. Technical success, defined as the ability to achieve final residual angiographic stenosis no greater than 30%.

10. Clinical success at follow-up is defined as an improvement of Rutherford classification at 1-, 6- and 12-month follow-up of one class or more as compared to the pre-procedure Rutherford classification.

Study description

Background summary

Helping patients with peripheral arterial disease in the iliac arteries

Study objective

The objective of this clinical investigation is to evaluate, in a controlled setting, the long-term (up to 12 months) safety and efficacy of the Solaris Vascular Stent Graft (Scitech) in clinical settings
when used according to the indications of the IFU.

Study design

Prospective, multi-center, controlled physician-sponsored clinical study

Study burden and risks

not applicable. everything according to standard of care (treatment and follow-up schedule)

Contacts

Public
FCRE - Foundation for Cardiovascular Research and Education

Plaggenbahn 6
Bottrop 46242
DE
Scientific
FCRE - Foundation for Cardiovascular Research and Education

Plaggenbahn 6
Bottrop 46242
DE

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patient presenting with a stenotic or occlusive lesion at the iliac arteries suitable for stenting
Patient presenting with a score from 2 to 5 following Rutherford Classification
Patient is willing to comply with specified follow-up evaluations at the specified times for the duration of the study

Patient is >18 years old
Patient (or their legal representative) understands the nature of the procedure and provides written informed consent, prior to enrolment in the study
Patient is eligible for treatment with the SOLARIS® Vascular Stent Graft (Scitech Medical)

Exclusion criteria

PTA is technically not possible (not feasible to access the lesion or a defect with the guidewire or balloon catheter)
Presence of an aneurysm immediately adjacent to the site of stent implantation
Stenosis distal to the site of stent implantation
Lesions in or adjacent to essential collaterals(s)
Lesions in locations subject to external compression
Heavily calcified lesions resistant to PTA
Patients with diffuse distal disease resulting in poor stent outflow
Patients with a history of coagulation disorders
Patients with aspirin allergy or bleeding complications and patients unable or unwilling to tolerate anticoagulant/antiplatelet therapy and/or non-responders to anticoagulant/antiplatelet therapy
Fresh thrombus formation
Patients with known hypersensitivity to the stent material (L605) and/or PTFE
Previously implanted stent(s) at the same lesion site
Reference segment diameter is not suitable for the available stent design
Untreatable lesion located at the distal outflow arteries
Use of alternative therapy (e.g. atherectomy, cutting balloon, laser, radiation therapy) as part of the index procedure
Patients refusing treatment
Patients for whom antiplatelet therapy, anticoagulants or thrombolytic drugs are contraindicated
- Patients who exhibit persistent acute intraluminal thrombus of the proposed lesion site
- Perforation at the angioplasty site evidenced by extravasation of contrast medium
- Patients with a history of prior life-threatening contrast medium reaction
- Patients with uncorrected bleeding disorders
- Female patient with childbearing potential not taking adequate contraceptives
- Life expectancy of less than twelve months
- Any planned surgical intervention/procedure within 30 days of the study procedure
- Any patient considered to be hemodynamically unstable at onset of procedure
- Patient is currently participating in another investigational drug or device study that has not
completed the entire follow up period.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-01-2022
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	SOLARIS vascular stent Graft
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	25-05-2021
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	12-08-2024
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NCT04299906
CCMO	NL75935.100.20