Drug Eluting Scaffold with an absorbable platform for primary lower extremity arterial revascularization

Published: 01-03-2017
Last updated: 14-04-2024

The primary objective of the study is to assess the safety and performance of Akesys Prava Sirolimus Eluting Bioresorbable Peripheral scaffold system (Akesys Prava

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

Summary

ID

NL-OMON42932

Source
ToetsingOnline

Brief title
DESappear

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
peripheral arterial disease /symptomatic primary atherosclerotic stenoses and occlusions of the superficial femoral artery (SFA)

Research involving
Human

Sponsors and support

Primary sponsor: Elixir Medical Corporation
Source(s) of monetary or material Support: Industrie

Intervention

Keyword: Drug Eluting Scaffold, lower extrimities, PAD, Resorbable

Outcome measures

Primary outcome

The primary safety endpoint is the composite of freedom from perioperative death (through 30-day follow-up) and freedom from major adverse limb events defined as the occurrence of major amputation, thrombectomy or thrombolysis, or major open surgical revascularization through 6-month follow-up

The primary effectiveness endpoint is primary patency defined as freedom from restenosis (>50% diameter reduction defined by Duplex Ultrasound) or clinically driven target lesion revascularization through 6 months.

Secondary outcome

* The composites for the primary safety and effectiveness endpoints will be tabulated through 12 months as secondary endpoints;

* Technical success; defined at the conclusion of the index procedure as a) successful delivery and deployment of the study device, b) <30% residual stenosis, and c) no metallic

* All-cause mortality;

* Major target extremity amputation;

* Minor target extremity amputations;

* Scaffold thrombosis;

* TL binary restenosis by duplex ultrasound (PSVR >2.4;

* Target Lesion Revascularization (TLR) (all);

* Clinically-driven TLR;

* Target extremity revascularization;

* Primary patency of the target lesion (TL);

* Primary-assisted patency of the TL;

* Secondary patency of the TL;

* Rutherford-Becker clinical category;

* Ankle brachial index (ABI) in the target extremity;

* Walking capacity as demonstrated by Walking Impairment Questionnaire (WIQ)

scores;

* Quality of Life Measures using VASCUQOL (disease specific);

* Duplex ultrasound-derived Peak Systolic Velocity (PSV) at the TL;

* Binary restenosis as determined by duplex ultrasound PSVR >2.4.

Study description

Background summary

During angioplasty treatment of a blockage or narrowing of the artery in the upper leg, a balloon is used for dilation of the the blockage or narrowing of the artery. A stent is placed in order to reduce the risk of the vessel wall, to re-occlude with narrowing of the artery as result. However, in a substantial proportion of people who have undergone this treatment, re-occlusion of the vessels is seen after a while, in some cases leading to a new intervention. In some patiens, narrowing at the location of the stent occurs. A potential issue associated with metal stents, with or without drug coatings, is the permanent nature of the metallic device in the artery. By moving the leg, the metal stents can break in the thigh artery and also leading to scarring of the blood vessel and thereby leading to re-stenoses. In addition, the bare metal stent can limit the possibilities later on should a bypass surgery in the leg be needed. Therefore, Elixir, as well as other companies have designed non-permanent scaffolds (stents) that will be completely absorbed by the body over a period of time, similar to dissolving stitches. With implantation of a bioresorbable drug-eluting scaffold, the treatment goal is to open the narrow area in your artery, deliver small amounts of drug locally which will help prevent re-narrowing in this same area and finally, allow the scaffold itself

will reabsorb over time; essentially leaving nothing behind.

Study objective

The primary objective of the study is to assess the safety and performance of Akesys Prava Sirolimus Eluting Bioresorbable Peripheral scaffold system (Akesys Prava

Study design

Prospective, multicenter, single-arm study

Intervention

treatment of symptomatic primary atherosclerotic stenoses and occlusions of the superficial femoral artery (SFA)

Study burden and risks

Patients will be asked to take the standard medication for patients with the same disease who have undergone endovascular treatment. This may include aspirin, clopidogrel, prasugrel or ticagrelor. This medication is used to prevent blood clotting and must be taken for at least 1 year after the procedure.
The treatment procedure and follow-up visits are similar to standard medical care, except for the follow-up visit at 6 months, 24 months and 36 months after the procedure. Not standard two questionnaires that the patients at different time points have to fill during the study: WIQ (walking impairment questionnaire) and Quality of Life Questionnaire. time points: pre-procedure, 30 days, 6 months, 12 months, 24 months and 36 months follow-up.

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

Subject is diagnosed as having symptomatic claudication (Rutherford-Becker Clinical Category 2-4)
A single, de novo native disease segment of the SFA

Exclusion criteria

1. Previous bypass surgery or stenting at the target leasion (TL)
2. Percutaneous or open surgical revascularization of the contralateral iliac or infrainguinal arteries *30 days prior to the planned index procedure. Iliac artery lesions may be treated during the index procedure if necessary for approach to the TL;
3. Failure to successfully cross the target lesion with a guide wire;

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-09-2017
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	Akesys Prava TM
Registration:	No

Ethics review

Approved WMO Date:	23-03-2017
Application type:	First submission
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
CCMO	NL58385.100.16