A clinical study investigating the safety, efficacy and performance of the URECA CTO device.

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The objective of the clinical investigation is to investigate the safety and efficacy of the URECA CTO device in facilitating guidewire re-entry into the true lumen after passing occlusion(s) in the peripheral vasculature.

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

Summary

ID

NL-OMON55292

Source
ToetsingOnline

Brief title
URECA

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
Arteriosclerosis, Chronic Total Occlusion(s)

Research involving
Human

Sponsors and support

Primary sponsor: Ureca B.V.
Source(s) of monetary or material Support: Ureca BV.

Intervention

Keyword: Chronic Total Occlusion(s), First in man, Peripheral Arterial Disease (PAD), URECA CTO Device

Outcome measures

Primary outcome

- The primary efficacy endpoint is device success, defined as the successful placement of a guidewire in the true lumen distal of the CTO using the URECA CTO Device with or without a reentry device, without the occurrence of device related complications that involve a Serious Adverse Event.

- The primary safety endpoint is the absence of device related Serious Adverse Events.

The study is considered successful if the guidewire is placed correctly in the true lumen behind the occlusion in at least 80% of the patients and there are no more than 10% Serious Adverse Events, with the exception of (possible) device related death. In the case of (possible) device related death the study will put on hold until the DSMB has discussed the case and considers the device save to continue.

Secondary outcome

The secondary endpoints are:

* The successful placement of a guidewire in the true lumen distal of the CTO using the URECA CTO Device.

* The (per subject) occurrence of device related complications that involve a Serious Adverse Event.

* (Serious) Adverse Events (up to close out visit)

Adverse Events will be reported according at least to:

-if Adverse Event is Serious

-if Adverse Event is procedure related

-If Adverse Event is device related Expected

(Serious) Adverse Events include, but are not limited to:

* (S)AE resulting in Death

* Vessel perforation Distal vessel occlusion (thrombosis)

* Bleeding complications requiring transfusion

* Amputation

* Procedure Time (for complete procedure)

* Procedure Time (related to URECA CTO device)

* Total Fluoroscopy Time

* Total Contrast Load

Study description

Background summary

Peripheral Arterial Disease (PAD) restricts blood supply to the lower limbs. The disease causes obstructions that can affect blood vessels in both the proximal and distal regions. When these vessel obstructions exist for more than 3- 6 Months they are classed as chronic total occlusions. Without sufficient collateral formation this can lead to to chronic limb-treatening ischemia (CLTI), which is characterized by chronic pain and tissue loss. Without

revascularization this frequently leads to amputation.

This is the first clinical investigation of the URECA CTO Device in humans. At present, the device is not registered or placed on the market in any country, state or region. The URECA CTO device is intended to provide at least an equivalent result compared to existing catheter interventions for crossing (calcified) occluded vessels either via sub-intimal re-entry or spontaneous re-entry for the placement of a guidewire which facilitates various treatment options in patients with peripheral vascular disease. In the patient population of this clinical study, the URECA CTO device will introduce no new or additional safety risks beyond those associated with in the field widely used standard recanalization techniques, including recanalization via the subintimal route.

Study objective

The objective of the clinical investigation is to investigate the safety and efficacy of the URECA CTO device in facilitating guidewire re-entry into the true lumen after passing occlusion(s) in the peripheral vasculature.

Study design

This is a prospective, open-label, multicenter, two arm study, the arms being the 65 cm (short) URECA CTO device and the 115 cm (long) URECA CTO device. For the long device 10 subjects will be enrolled. For the short device 30 patients will be enrolled. Of these 30 patients we expect a re-entry procedure for approximately 10 patients. Taking into account a maximum attrition rate of 9% through withdrawal or lost to follow-up 11 subjects for the long device and 33 for the short device are expected to be enrolled before the required number of subjects is reached. There will be no randomization procedure, the treating physician will decide which device will be used (short or long) depending on the procedure. The use of a short or long device depends on the distance between the access site and the occlusion, It is not always technically possible to enter in the direction of the occlusion and the practitioner is forced to gain access on the contralateral side (retrograde approach) (see 7.2).

Intervention

Individual subjects will be followed-up post procedure, one week after the procedure. The safety is measured via SAEs documented during the procedure until the close-out visit. It is anticipated that enrollment, follow-up and the close-out study report will take approximately 18 months to be completed.

Study burden and risks

Participation in the study will last a total of 6 weeks for the patient. At time of the screening, blood tests will be done and a physical examination will be performed (such as blood pressure and heart rate). A quality of life questionnaire will also be conducted during the screening.

There are 2 follow-up checks after the procedure.
- Follow-up visit within 1 week after the procedure. During this 1 hour visit a physical examination will be performed and an ultrasound will be made. Possible side effects can also be discussed.
- Close-out visit by telephone within 4-6 weeks after the procedure. Prior to this telephone call a quality of life questionnaire will be sent to the patient. Compilation of the questionnaire will take approximately 15 minutes.

The associated risks presented in this study are similar to those of other interventional and vascular surgical procedures.

Physical risks associated with catheter placement:
* Death (<1%)
* Bleeding (1-2%)
* Arterial thromboembolism (blood clot in another) (<1%)
* Sepsis (blood infection) (1%)
* Infection of the puncture point (1%)
* Perforation (a hole in the wall of a blood vessel, vein or organ) (1%)
* Vascular injury (damage to a blood vessel) (1%)
* Venous thrombosis (blood clot in a blood vessel) (1%)
* Amputation
* Allergic reaction to contrast agent (<1%)

Risks related to anticoagulant medication:
* Bleeding problems
* Headache
* Dizziness
* Pain or discomfort
* Bruising
* Swelling
* Blood in urine or stool
* More bleeding than normal during menstruation
* Change in body temperature
* Visible dark areas on arms or legs

In addition to the general risks, the specific risks associated with the URECA are:
* Perforation (a hole in the wall of a blood vessel, vein or organ)
* Vascular injury (damage to a blood vessel)
* Arterial thromboembolism
* Release a part of the URECA

The benefit to the subjects enrolled in this study is the potential for improved blood flow to the foot reducing or eliminating the need for bypass surgery or in the worst case amputation.The potential benefit of reduced bypass surgery, procedures times, fluoroscopy and contrast loads and in the worst case scenario amputation of the foot greatly outweighs the standard endovascular/surgical risks associated with this procedure.

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. Subject must be ><= 18 and <<= 85 years old
2. Clinically diagnosed for endovascular treatment of peripheral vascular disease and chronic total occlusion in the iliac artery, superficial femoral artery or in the popliteal artery determined by duplex, CTA, MRA and/or DSA.

3. Patient has been assessed by an independent vascular surgeon and an interventional radiologist
4. Written and signed informed consent.

Exclusion criteria

1. Concomitant hepatic insufficiency, thrombophlebitis, deep venous thrombus, coagulation disorder or receiving immunosuppressant therapy;
2. Severe infection or soft tissue loss that may preclude any meaningful attempt at limb salvage;
3. Known or suspected allergies or contraindications to contrast agents;
4. Any significant medical condition which, in the investigator's opinion, may interfere with the subject's optimal participation in the study;
5. The subject is currently participating in another investigational drug or device study that has not completed the primary endpoint or that clinically interferes with the endpoints of this study;
6. Patient unable to give consent;
7. Pregnant and breastfeeding women;
8. Patients who recently suffered from a stroke and/or a myocardial infarct (Within 2 months)
9. Patients with an uncontrollable diabetes;
10. Severe intercurrent illness that, in the opinion of the investigator, may put the subject at risk when participating in the study
11. Patients with hypercoagulopathy;
12. Stent in place in the to be treated artery, unless stent is open, placed more then 6 months before and can be safely passed in the investigator's opinion.

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):	08-12-2020
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	07-07-2020
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	09-03-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	14-12-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NCT04385381
CCMO	NL73070.078.20