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First in human study of the thor laser system

Submission date 09/02/2016	**Recruitment status** Stopped	[X] Prospectively registered
		[ ] Protocol
Registration date 18/02/2016	**Overall study status** Stopped	[ ] Statistical analysis plan
		[ ] Results
Last Edited 31/08/2017	**Condition category** Circulatory System	[ ] Individual participant data
		[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Peripheral arterial disease (PAD) is a common condition in which the blood flow to the legs is restricted. This happens because of the buildup of a fatty substance (plaque) and calcium salts on walls of arteries, which becomes hardened (calcification) leading to reduced flow of blood through the blood vessels. Over time this can cause the main arteries in the legs, usually the femoral (thigh level) and/or popliteal (knee level) arteries, to become narrowed (stenosed) or blocked (occluded). This can cause a severe cramping pain in the legs when exercising (claudication), as the restricted blood flow cannot deliver enough oxygen to the leg muscles. As the arteries become narrower, patients begin the feel pain even when at rest and are at severe risk of developing ulcers or gangrene (critical limb ischaemia) or even having a heart attack or stroke. One of the most common treatments for stenosed arteries is a procedure called an angioplasty, in which a balloon is inflated inside the artery to flatten the blockage against the artery wall. This does not tend to be very effective when the lesion (blockage) is calcified however, as it means that it is hard and immovable. The Thor Laser System is a device which is uses bursts of ultraviolet (UV) light energy to vaporize (remove) blockages in the arteries. The aim of this study is to test to safety and effectiveness of using the Thor Laser System to break up calcium present in PAD.

Who can participate?
Adults aged between 18 and 80 years old with symptoms of PAD.

What does the study involve?
At the start of the study, all patients receive an angiogram and potentially an intravascular ultrasound (IVUS) scan (scanning techniques used to look inside of blood vessels), in order to assess the calcified lesion (blockage). Following this a small balloon is inflated inside the artery in order to see whether the lesion can be flattened against the artery wall. The Thor Laser System probe is then placed into the artery, and uses bursts of ultraviolet (UV) light energy to destroy the lesion. The balloon is then re-inflated inside the artery for 30 seconds in order to see if the Thor treatment means that the blockage can now be flattened. Participants undergo the angiogram and potentially IVUS again after the procedure, in order to see whether the treatment has worked or whether they require further operations.

What are the possible benefits and risks of participating?
Participants could benefit from a reduction in their PAD symptoms if the blockage is destroyed

by the Thor Laser System, which could lower their chances of needing future surgery or amputation, and improve their quality of life. There is a small risk of complications from the procedure, such as pain, swelling and bleeding. There is also a risk that in future, the cleared artery could become blocked again (restenosis).

Where is the study run from?
1. Swiss Cardiovascular Center (Switzerland)
2. Lugano Regional Hospital (Switzerland)

When is the study starting and how long is it expected to run for?
June 2016 to September 2016

Who is funding the study?
The Spectranetics Corporation (USA)

Who is the main contact?
1. Mrs Hailey Austin (public)
2. Mr Matt Stark (scientific)

Contact information

Type(s)
Public

Contact name
Mrs Hailey Austin

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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
D028737

Study information

Scientific Title
First in human study of the thor laser system: A prospective first in human study to evaluate the safety and performance of the thor laser system in the treatment of calcified lesions

Study objectives
The aim of this early feasibility study is to evaluate the safety and effectiveness of the Thor Laser System in disrupting calcium in non-dilatable lesions in the intimal and medial space of arteries.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration.

Study design
Multi-center non-randomised study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No specific participant information sheet available, please use the contact details below to request a further information.

Health condition(s) or problem(s) studied
Stenotic or occlusive disease in the infrainguinal arteries, with moderate to severe calcified lesions by visual angiography.

Interventions
Patients will be prepped as standard of care at the facility and undergo angiography and potentially intravascular ultrasound (IVUS) scans so that the lesion can be visualised. A semi-

compliant balloon will be inflated to 4 atm and held for 30 seconds to determine whether the lesion is resistant to the balloon. The investigational system (Thor Laser System) will then be inserted and therapy will be delivered to the target lesion. The same balloon is reinserted and inflated to 4atm and held for 30 seconds to determine vessel compliance post Thor. Treatment with Thor only takes a few minutes, varying upon length of lesion to be treated. Participants will then repeat angiography and potentially intravascular ultrasound (IVUS) scans at the end of the procedure.

Intervention Type
Device

Primary outcome measure
1. Minimum arterial lumen diameter is measured using angiographic at baseline and post-Thor treatment
2. The ability to dilate a previously balloon-resistant lesion after Thor treatment with low pressure balloon inflation is recorded during procedure
3. Any MAE, defined as death from any cause, repeat target vessel revascularization with endovascular intervention or bypass surgery, or amputation of target limb through 30-day follow-up (total of 37 days)

Secondary outcome measures
1. Calcification score is a visual assessment by using angiographic at baseline and post-Thor treatment
2. Angiographic success (defined as <30% residual stenosis) is a visual assessment by angiography at baseline and post-Thor treatment
3. Rate of procedural adverse events are measured by visual inspection of angiograms during procedure

Overall study start date
01/06/2016

Completion date
30/09/2016

Reason abandoned (if study stopped)
Business decision

Eligibility

Key inclusion criteria
1. Patient aged between 18 and 80 years
2. Patient agrees to participate and comply with the protocol by signing a Medical Ethics Committee approved consent form
3. Subject meets the criteria for treatment according to Instructions for Use (IFU)
4. Peripheral arterial disease with a documented Rutherford Class 2-5
5. Moderate or severe calcium to include fluoroscopic evidence of calcification:
5.1.On parallel sides of the vessel
5.2. Extending ≥50% the length of the balloon
6. Balloon resistant calcific lesion apparent on angiogram by inability to dilatate lesion to less than 50% DS
7. De novo or restenotic lesion of the SFA, popliteal or tibial artery

8. Reference vessel diameter 3.0-6.5mm
9. At least one patent runoff vessel to the foot

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
20

Key exclusion criteria
1. Patient is pregnant or breast feeding (Female subjects of childbearing potential must have negative serum pregnancy test 7 days prior to treatment)
2. Life expectancy < 12 months
3. Evidence of Acute Limb Ischemia within 7 days prior to procedure
4. CVA < 60 days prior to procedure.
5. Myocardial infarction < 60 days prior to procedure.
6. Known contraindication to aspirin, antiplatelet/anti-coagulant therapies required for procedure/follow up.
7. Known allergy to contrast media that cannot adequately be pre-medicated prior to study procedure.
8. Uncontrolled hypercoagulability or history of HIT or HITTS syndrome
9. Serum creatinine ≥ 2.5 mg/dL tested within a week prior to procedure
10. Patient is simultaneously participating in another investigational drug or device study that will interfere with the 30 day Safety Endpoint
11. Patient is not eligible for bypass surgery or endovascular intervention
12. Planned major amputation
13. Lesion located within a stent or endograft
14. Planned or predicted cardiovascular surgical or interventional procedures prior to completion of the 30–day follow–up (including, but not limited to aortic, renal, cardiac, carotid, contralateral femoropopliteal, and contralateral below the knee
15. Ipsilateral and/or contralateral iliac (or common femoral) artery stenosis ≥50% DS that is not successfully treated prior to index procedure
16. Target lesion could not be crossed with the guidewire or support catheter
17. Target lesion length(s) exceed 200mm

Date of first enrolment
01/06/2016

Date of final enrolment
31/08/2016

Locations

Countries of recruitment

Switzerland

Study participating centre
Swiss Cardiovascular Center
University Hospital
Freiburgstrasse
Bern
Switzerland
3010

Study participating centre
Lugano Regional Hospital (Ospedale Regionale di Lugano)
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Sponsor information

Organisation
The Spectranetics Corporation (USA)

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Sponsor type
Industry

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Funder(s)

Funder type
Industry

Funder Name
The Spectranetics Corporation (USA)

Results and Publications

Publication and dissemination plan
Planned publication in a peer reviewed journal.

Intention to publish date
31/12/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request