

First in human study of the thor laser system

Submission date 09/02/2016	Recruitment status Stopped	☒ 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 to 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 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

Contact details

The Spectranetics Corporation
9965 Federal Drive
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Type(s)

Scientific

Contact name

Mr Matt Stark

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Additional identifiers

Protocol serial number

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.

Primary study design

Interventional

Study design

Multi-center non-randomised study

Study type(s)

Treatment

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(s)

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)

Key secondary outcome(s)

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

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 $\geq 50\%$ the length of the balloon

6. Balloon resistant calcific lesion apparent on angiogram by inability to dilate 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

Healthy volunteers allowed

No

Age group

Mixed

Sex

All

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 $\geq 50\%$ 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)
Via Tesserete 46
Lugano
Switzerland
6900

Sponsor information

Organisation

The Spectranetics Corporation (USA)

ROR

<https://ror.org/03kw6wr76>

Funder(s)

Funder type

Industry

Funder Name

The Spectranetics Corporation (USA)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request