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Bioabsorbable stent implantation versus endarterectomy for atherosclerotic lesions in the common femoral artery

Submission date
12/05/2013

Recruitment status
No longer recruiting

Registration date
04/09/2013

Overall study status
Completed

Last Edited
12/05/2015

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Relief of peripheral arterial occlusive disease (a narrowing of the blood vessels commonly seen in the legs sometimes seen in the arms) can be achieved either by open surgical interventions or minimally invasive percutaneous interventions (a medical procedure where access to inner organs or other tissue is done through a needle-puncture of the skin). The groin artery is a difficult artery to deal with, especially due to its location, and open surgery, although durable, can lead to long-lasting wound healing problems. Stent (a small mesh tube) implantation in that region has long been avoided, due to the fact that stents may be deformed, and later access for open and endovascular interventions (surgery that accesses regions inside the body via major blood vessels) may be difficult. A bioabsorbable stent may overcome these problems, as it dissolves within a defined time period (8 months), thus leaving the artery without foreign body, and accessible for open surgery and percutaneous intervention.

Who can participate?
Patients with peripheral arterial occlusive disease in the common femoral artery (artery in the thigh) due to thickening of the artery wall (atherosclerosis).

What does the study involve?
Patients requiring a common femoral artery intervention will be randomly allocated after informed consent into one of the two arms: open surgery or stent placement.

What are the possible benefits and risks of participating?
Both procedures are performed routinely at the department, there are no special risks involved for the patients taking part in this trial.

Where is the study run from?
Paracelsus Medical University, Austria.

When is the study starting and how long is it expected to run for?
The study started in May 2011 and will run until January 2017.

Who is funding the study?
Kyoto Medical planning.

Who is the main contact?
Prof Thomas Hölzenbein

Contact information

Type(s)
Scientific

Contact name
Prof Thomas Hölzenbein

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Bioabsorbable stent implantation versus endarterectomy for atherosclerotic lesions in the common femoral artery: an open prospective randomized trial

Study objectives
Stent implantation in the femoral artery is an accepted treatment for short atherosclerotic lesions. It is minimally invasive, and can be done under local anesthesia with very short hospital stay. Yet stent implantation in the groin artery carries the risk for stent deformation and subsequent stent failure. Surgery is more durable, yet more invasive, and carries more perioperative complications (infection, bleeding). Our study hypothesis is that, a bioabsorbable stent may overcome the disadvantages of stent deformation, and will not impede later endovascular or open surgery of the groin artery because the stent dissolves within 8 months. Therefore, stent treatment with a bioabsorbable stent may become a better therapeutic option than open surgery.

On 28/01/2014 the overall trial start date was changed from 01/01/2013 to 01/05/2011.

On 13/11/2014 the target number of participants was changed from 120 (60 per group) to 214 (107 per group).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local research ethics committee, PMU Salzburg, Austria, 16/09/2013, ref: 415-E/1657/3-2013

Study design
Open prospective randomized trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Atherosclerosis. Peripheral arterial occlusive disease. Fontaine stages IIb-IV

Interventions
1. Standard common femoral artery endarterectomy with patch closure (vein/artificial)
2. Percutaneous common femoral artery stent implantation using a bioabsorbable lactic acid stent

Intervention Type
Procedure/Surgery

Primary outcome measure
Current primary outcome measures as of 28/01/2014:
1. Surgical site infections (SSI, local groin complications associated with intervention, i.e. wound healing, bleeding, infection)

Outcomes are measured regularly at baseline, one month, 3 months, 6 months and biannually thereafter

Previous primary outcome measures:
1. Intervention patency

2. Effect of intervention (improvement of circulation as measuerd by the ankle/brachial index)
3. Limb salvage
4. Survival

Outcomes are measured regularly at baseline, 1 month, 3 months, 6 months and biannually thereafter

Secondary outcome measures
Current secondary outcome measures as of 28/01/2014:
1. Technical success
2. Hemodynamic improvement (measured by ankle-brachial index)
3. Primary sustained clinical improvement (relief of symptoms measured by standard forms, e.g. SF19)
4. Secondary sustained clinical improvement (relief of symptoms measured by standard forms, e. g. SF19)
5. Patency
6. Limb salvage
7. Hospital resource use (length of stay, outpatient clinic visits, costs)
8. Survival

Outcomes are measured regularly at baseline, 1 month, 3 months, 6 months and biannually thereafter

Previous secondary outcome measures:
1. Local groin complications associated with intervention (wound healing, bleeding, infection)
2. Relief of symptoms (measured by standard forms e.g. SF19)
3. Hospital resource use (length of stay, outpatient clinic visits, costs)
4. Secondary intervention for improvement of circulation

Outcomes are measured regularly at baseline, 1 month, 3 months, 6 months and biannually thereafter

Overall study start date
01/05/2011

Completion date
31/01/2017

Eligibility

Key inclusion criteria
Patients with peripheral arterial occlusive disease in the common femoral artery due to atheroscloerosis

Participant type(s)
Patient

Age group
Adult

Sex

Both

Target number of participants
214 (107 per group)

Key exclusion criteria
1. Pregnancy
2. Active malignancy
3. Infectious diseases (hepatitis, HIV)
4. Inability to comply with study requirements (e.g. regular follow up)

Date of first enrolment
01/05/2011

Date of final enrolment
31/01/2017

Locations

Countries of recruitment
Austria

Study participating centre
PMU Salzburg
Salzburg
Austria
A-5020

Sponsor information

Organisation
Paracelsus Medical University (PMU) (Paracelsus Medizinische Privatuniversität) (Austria)

Sponsor details
c/o Prof Thomas Hölzenbein
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Sponsor type
University/education

ROR

https://ror.org/03z3mg085

Funder(s)

Funder type
Industry

Funder Name
Kyoto Medical planning (An insurance regarding adverse outcomes) (Japan)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2014		Yes	No