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Evaluation of external beam radiation to prevent restenosis after femoropopliteal stenting

Submission date 24/02/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 24/02/2006	**Overall study status** Completed	
Last Edited 04/03/2009	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
MCT-78566

Study information

Scientific Title

Prospective, multicentre, randomised double blinded evaluation of external beam radiation to prevent restenosis after femoropopliteal stenting to treat atherosclerotic stenosis or occlusion of femoropopliteal arteries

Study objectives
The external beam radiation will significantly increase the arterial lumen diameter at the treatment site, two years after stenting and will lead to an improvement of the ankle-brachial index.

As of 16/07/2008, this trial record has been updated, and changes to the inclusion and exclusion criteria performed. For more details, please see all changes in these fields under the above update date.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Comités d'evaluation scientifique et d'éthique de la recherche, Équipe Hôpital Notre-Dame du CHUM, Montréal, Québec (Canada) approved on the 9th September 2005.

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Peripheral vascular disease/femoropopliteal artery obstruction

Interventions
1. Femoropopliteal stenting: Group A and B
2. External radiation (24 hours post-stenting): Group A
3. Clinical follow-up, evaluation of side effects, ankle-brachial index and Doppler ultrasound (every 6 months): Group A and B
4. Angiography (at 24 months): Group A and B

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
A lower restenosis rate (greater than or equal to 50%) in the radiation group than in the control group, as measured by angiography 24 months after stenting

Key secondary outcome(s))

A higher ankle-brachial index, a lower reintervention rate, and a lower amputation rate in the radiation group, with similar side-effects and complications in both groups

Completion date
30/09/2010

Eligibility

Key inclusion criteria
Current inclusion criteria as of 16/07/2008:
1. 45 years and older, either sex
2. Femoropopliteal lesion greater than 4 cm above knee joint
3. Symptomatic lesion category 2 - 6 on Rutherford scale
4. Thrombosis or stenosis greater than 70% category A, B or C
5. Restenotic or de novo lesion, less than or equal to 20 cm
6. Ipsilateral ankle-brachial index (ABI) at rest less than or equal to 0.95
7. Written informed consent

Previous inclusion criteria:
1. 45 years and older, either sex
2. Femoropopliteal lesion greater than 4 cm above knee joint
3. Symptomatic lesion category 2 - 6 on Rutherford scale
4. Thrombosis or stenosis greater than 70% category A, B or C
5. Restenotic or de novo lesion, less than 15 cm
6. Ipsilateral ankle-brachial index (ABI) at rest less than or equal to 0.85
7. Written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Current exclusion criteria as of 16/07/2008:
1. Contraindication to angiography or angioplasty or to clopidogrel
2. Recurrent lesion already treated by stenting
3. Prior irradiation or infection to the expected radiation site
4. Prior use of doxorubicine or other radiosensibilising agent
5. Patient susceptible to be pregnant
6. Hemodynamically significant lesion above the femoropopliteal lesion
7. Inhability to give informed consent or to complete the follow-up
8. Life expectancy of less than 2 years
9. Superficial femoral lesion treated with a view to a lower limb bypass initiated below site of

femoro-popliteal endovascular revascularisation
10. Femoro-popliteal lesion located at least 2 cm below the groin (4 cm in the case of obese patients). For purposes of radiography the lesion should be located at 2 cm (4 cm in the case of obese patients) below the lower edge of the femoral head.

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5. Patient susceptible to be pregnant
6. Hemodynamically significant lesion above the femoropopliteal lesion
7. Inhability to give informed consent or to complete the follow-up
8. Life expectancy of less than 2 years

Date of first enrolment
01/10/2005

Date of final enrolment
30/09/2010

Locations

Countries of recruitment
Canada

Study participating centre
Hôtel-Dieu du CHUM
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Sponsor information

Organisation
Hôtel-Dieu de Montréal (Canada)

ROR
https://ror.org/0468gx405

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-78566)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration