

Evaluation of external beam radiation to prevent restenosis after femoropopliteal stenting

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Eric Therasse

Contact details
Hôtel-Dieu du CHUM
Département de Radiologie
3840 St-Urbain
Montreal
Canada
H2W 1T8
+1 514 890 8150
eric.therasse.chum@ssss.gouv.qc.ca

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

Primary study design

Interventional

Study design

Randomised controlled trial

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. Inability 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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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

Montreal

Canada

H2W 1T8

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