# Evaluation of external beam radiation to prevent restenosis after femoropopliteal stenting

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

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

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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.

#### Previous exclusion criteria:

- 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

#### 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

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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

**Study outputs** 

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet
Participant information sheet
11/11/2025 No Yes