

Prospective randomised controlled trial of femoropopliteal stenting in patients with critical ischaemia

Submission date 12/09/2003	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/09/2003	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 05/12/2014	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0199119925

Study information

Scientific Title

Prospective randomised controlled trial of femoropopliteal stenting in patients with critical ischaemia

Study objectives

In patients with critical ischaemia, does femoropopliteal stenting improve patient outcome over angioplasty?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Cardiovascular: Critical ischaemia

Interventions

Femoropopliteal stenting vs angioplasty

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1. Patency of superficial femoral and popliteal artery at 6 and 12 months
2. Wound healing. Need for further revascularisation

- 3. Amputation (level)
- 4. Morbidity and mortality

Secondary outcome measures

Not provided at time of registration

Overall study start date

09/10/2002

Completion date

31/08/2004

Eligibility

Key inclusion criteria

110 adults - 55 in each arm - if angiogram shows stenosis or occlusion in femoral or popliteal arteries, lesion is amenable to angioplasty and therefore IIS, angioplasty is first line treatment.

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

110

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

09/10/2002

Date of final enrolment

31/08/2004

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Royal Berkshire Hospital
Reading
United Kingdom
RG1 5AN

Sponsor information

Organisation

Department of Health (UK)

Sponsor details

Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type

Government

Website

<http://www.doh.gov.uk>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Royal Berkshire and Battle Hospitals NHS Trust (UK)

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