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

Submission date 12/09/2003	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 05/12/2014	**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

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 femoropoliteal 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
Femoropoliteal 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