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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

Protocol serial number
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

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Cardiovascular: Critical ischaemia

Interventions
Femoropoliteal stenting vs angioplasty

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
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

Key secondary outcome(s))
Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

England

Study participating centre
Royal Berkshire Hospital
Reading
United Kingdom
RG1 5AN

Sponsor information

Organisation
Department of Health (UK)

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Royal Berkshire and Battle Hospitals NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration