

Multi-centre randomised controlled trial of the cost-effectiveness of infra-inguinal percutaneous transluminal angioplasty (PTA) versus reconstructive surgery for severe limb ischaemia

Submission date 25/04/2003	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 25/04/2003	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 21/06/2010	Condition category Circulatory System	☐ Individual participant data

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

Study information

Scientific Title

Acronym

BASIL

Study objectives

To determine by means of a multi-centre, randomised controlled trial whether, in patients with severe lower limb ischaemia, adopting a 'PTA first' strategy rather than the traditional 'surgery first' strategy is associated with a better outcome in terms of:

- a. A reduction on all-cause mortality and requirement for major limb amputation (primary clinical end-points)
- b. Abolition of symptoms, procedure complications, secondary and cross-over interventions, minor amputation, quality of life measures and cost-effective utilisation of NHS resources (secondary end-points)

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)

Not Specified

Health condition(s) or problem(s) studied

Cardiovascular diseases: Peripheral arterial disease

Interventions

Please note that, as of 15 January 2008, the end date of this trial has been updated from 31 January 2004 to 31 December 2007.

Interventions:

1. Percutaneous transluminal angioplasty (PTA)
2. Standard reconstructive surgery

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

1. A reduction on all-cause mortality and requirement for major limb amputation (primary clinical end-points)
2. Abolition of symptoms, procedure complications, secondary and cross-over interventions, minor amputation, quality of life measures and cost-effective utilisation of NHS resources (secondary end-points)

Key secondary outcome(s))

Not provided at time of registration.

Completion date

31/12/2007

Eligibility

Key inclusion criteria

Not provided at time of registration.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/03/1999

Date of final enrolment

31/12/2007

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
University Department of Vascular Surgery
Birmingham
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Sponsor information

Organisation
Department of Health (UK)

ROR
<https://ror.org/03sbpja79>

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK)

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?
Results article	results on clinical and cost-effectiveness	01/03/2010		Yes	No
Results article	results of analysis of amputation free and overall survival by treatment received	01/05/2010		Yes	No
Results article	results of health-related quality of life outcomes, resource utilization, and cost-effectiveness analysis	01/05/2010		Yes	No
Results article	results of intention-to-treat analysis of amputation-free and overall survival in patients	01/05/2010		Yes	No

Results article	results on a survival prediction model to facilitate clinical decision making	01/05/2010	Yes	No
Results article	results on severity and extent of disease	01/05/2010	Yes	No
Other publications	interim analysis	03/12/2005	Yes	No
Other publications	trial discussion	01/05/2010	Yes	No
Other publications	trial in perspective	01/05/2010	Yes	No