

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 25/04/2003	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 21/06/2010	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Andrew Bradbury

Contact details
University Department of Vascular Surgery
Solihull Hospital
Flat 5, Netherwood House
Lode Lane
Solihull
Birmingham
United Kingdom
B91 2JL
+44 (0)121 424 5086
Andrew.Bradbury@heartofengland.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

HTA 96/05/01

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

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 measure

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)

Secondary outcome measures

Not provided at time of registration.

Overall study start date

01/03/1999

Completion date

31/12/2007

Eligibility

Key inclusion criteria

Not provided at time of registration.

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

452

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

England

United Kingdom

Study participating centre

University Department of Vascular Surgery

Birmingham

United Kingdom

B91 2JL

Sponsor information

Organisation

Department of Health (UK)

Sponsor details

Quarry House

Quarry Hill

Leeds

United Kingdom

LS2 7UE

+44 (0)1132 545 843

Sheila.Greener@doh.gsi.gov.uk

Sponsor type

Government

Website

<http://www.dh.gov.uk/en/index.htm>

ROR

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

Funder(s)

Funder type

Government

Funder Name

NIHR Health Technology Assessment Programme - HTA (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	interim analysis	03/12/2005		Yes	No
Results article	results on clinical and cost-effectiveness	01/03/2010		Yes	No
Other publications	trial discussion	01/05/2010		Yes	No
Other publications	trial in perspective	01/05/2010		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