

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

<b>Submission date</b> 25/04/2003	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 25/04/2003	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 21/06/2010	<b>Condition category</b> 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](mailto: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?
<a href="#">Other publications</a>	interim analysis	03/12/2005		Yes	No
<a href="#">Results article</a>	results on clinical and cost-effectiveness	01/03/2010		Yes	No
<a href="#">Other publications</a>	trial discussion	01/05/2010		Yes	No
<a href="#">Other publications</a>	trial in perspective	01/05/2010		Yes	No
<a href="#">Results article</a>	results of analysis of amputation free and overall survival by treatment received	01/05/2010		Yes	No
<a href="#">Results article</a>	results of health-related quality of life outcomes, resource utilization, and cost-effectiveness analysis	01/05/2010		Yes	No
<a href="#">Results article</a>	results of intention-to-treat analysis of amputation-free and overall survival in patients	01/05/2010		Yes	No
<a href="#">Results article</a>	results on a survival prediction model to facilitate clinical decision making	01/05/2010		Yes	No
<a href="#">Results article</a>	results on severity and extent of disease	01/05/2010		Yes	No