

# 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

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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  
United Kingdom  
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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?
<a href="#">Results article</a>	results on clinical and cost-effectiveness	01/03/2010		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
<a href="#">Other publications</a>	interim analysis	03/12/2005	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