

# A multicentre prospective randomised trial comparing angioplasty versus stenting for the management of iliac occlusions

<b>Submission date</b> 23/01/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 23/01/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 12/07/2013	<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 P Gaines

### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

# Study information

## Scientific Title

### Study objectives

Do iliac stents improve the safety and efficacy of treating iliac occlusions compared to 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

### Secondary study design

Randomised controlled trial

### Study setting(s)

Hospital

### Study type(s)

Treatment

### Participant information sheet

### Health condition(s) or problem(s) studied

Cardiovascular diseases: Peripheral arterial disease

### Interventions

1. Iliac stents
2. Angioplasty

### Intervention Type

Other

### Phase

Not Applicable

### Primary outcome measure

1. Primary success - residual gradient <10 mm mercury
2. Cost of initial treatment

3. Cost of hospital stays
4. Cost of re-intervention
5. Statistical analysis

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/09/1994

**Completion date**

01/02/2002

## Eligibility

**Key inclusion criteria**

1. Males and females above 18 years
2. Iliac artery/occlusion 8 cm or less.

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

140 patients, 40 patients over 1 year in Sheffield

**Key exclusion criteria**

Not provided at time of registration

**Date of first enrolment**

01/09/1994

**Date of final enrolment**

01/02/2002

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**  
**Sheffield Vascular Institute**  
Sheffield  
United Kingdom  
S5 7AU

## **Sponsor information**

### **Organisation**

NHS R&D Regional Programme Register - Department of Health (UK)

### **Sponsor details**

The Department of Health  
Richmond House  
79 Whitehall  
London  
United Kingdom  
SW1A 2NL  
+44 (0)20 7307 2622  
dhmail@doh.gsi.org.uk

### **Sponsor type**

Government

### **Website**

<http://www.doh.gov.uk>

## **Funder(s)**

### **Funder type**

Government

### **Funder Name**

NHS Executive Trent (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="#">Results article</a>	results	01/08/2013		Yes	No