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

Submission date 23/01/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/01/2004	**Overall study status** Completed	
Last Edited 12/07/2013	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof P Gaines

Contact details
Sheffield Vascular Institute
Northern General Hospital NHS Trust
Herries Road
Sheffield
United Kingdom
S5 7AU
+44 (0)114 2714345
p.a.gaines@sheffield.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

940028

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?
Results article	results	01/08/2013		Yes	No