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Distal embolisation during percutaneous coronary intervention - evaluation of contributory factors and analysis of embolic material

Submission date	Recruitment status	[_] Prospectively registered
12/09/2003	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/09/2003	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
12/01/2010	Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Daniel Blackman

Contact details
Department of Cardiology
John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU
+44 (0)1865 741166
Cardiology.registrars@orh.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0176115666

Study information

Scientific Title

Study objectives
The aim of this study is to assess distal embolisation during high-risk PCI, and to evaluate the factors which determine the degree of distal embolisation, measured according to the amount of material trapped in the collection filter. In particular we aim to determine whether the use of different types of stent influences the degree of distal embolisation. The secondary aim of this study is to perform analysis of material collected in the filter bag during PCI to provide insight into its make-up, and to compare its make-up in different patient groups.

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: Distal embolisation

Interventions
Use of Symbiot self-expanding stent or a conventional stent.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Primary endpoint: amount of distal embolisation determined by weight of material collected in distal protection device.

Secondary outcome measures
Secondary endpoints:
1. Troponin I at 12 h
2. Analysis of debris collected within distal protection device

Overall study start date
01/07/2002

Completion date
01/07/2003

Eligibility

Key inclusion criteria
1. Patients undergoing PCI (percutaneous coronary intervention) to saphenous vein grafts.
2. Patients undergoing PCI for an acute coronary syndrome. ≥15 mm length of vessel beyond lesion and before graft insertion or major side-branch of native vessel to allow placement of filter wire.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
100 patients

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/07/2002

Date of final enrolment
01/07/2003

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Department of Cardiology
Oxford
United Kingdom
OX3 9DU

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
Oxford Radcliffe Hospitals NHS Trust (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	01/11/2005		Yes	No