ISRCTN86339277 https://doi.org/10.1186/ISRCTN86339277

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

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

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
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

Study type(s)
Not Specified

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(s)
Primary endpoint: amount of distal embolisation determined by weight of material collected in distal protection device.

Key secondary outcome(s))
Secondary endpoints:
1. Troponin I at 12 h
2. Analysis of debris collected within distal protection device

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

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/07/2002

Date of final enrolment
01/07/2003

Locations

Countries of recruitment
United Kingdom

England

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

Sponsor information

Organisation
Department of Health (UK)

Funder(s)

Funder type
Government

Funder Name
Oxford Radcliffe Hospitals NHS Trust (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?
Results article	results	01/11/2005		Yes	No