

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
Registration date 12/09/2003	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 12/01/2010	Condition category Circulatory System	☐ 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

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