A pilot study to evaluate the efficacy of combined transplantation of progenitor cells and coronary artery bypass grafting

Submission date	Recruitment status	Prospectively registered
30/09/2004	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
30/09/2004	Completed	Results
Last Edited	Condition category	Individual participant data
26/07/2016	Surgery	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0231134600

Study information

Scientific Title

A pilot study to evaluate the efficacy of combined transplantation of progenitor cells and coronary artery bypass grafting (TOPCABG)

Study objectives

Can the transplanted progenitor cells promote improvements in myocardial function?

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

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Surgery: Coronary artery bypass grafting (CABG)

Interventions

Randomised controlled trial - 5 recipients receiving stem cells and 5 control patients receiving heparinised saline

Intervention Type

Procedure/Surgery

Phase

Not Applicable

Primary outcome measure

Improvements in myocardial function, regional wall motion and myocardial perfusion

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/01/2004

Completion date

01/01/2005

Eligibility

Key inclusion criteria

10 patients undergoing coronary artery bypass grafting

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

10

Key exclusion criteria

Does not match inclusion criteria

Date of first enrolment

01/01/2004

Date of final enrolment

01/01/2005

Locations

Countries of recruitment

England

United Kingdom

Study participating centre Southampton General Hospital

Southampton

Sponsor information

Organisation

Department of Health

Sponsor details

Richmond House 79 Whitehall London United Kingdom SW1A 2NL

Sponsor type

Government

Website

http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Southampton University 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