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Efficacy of the mode of delivery of autologous bone marrow cells into heart scar muscle for the recovery of contractile function

Submission date 30/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/09/2005	**Overall study status** Completed	
Last Edited 05/04/2011	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0523154398

Study information

Scientific Title

Study objectives
Study the efficacy of the intravascular as compared to intramuscular administration of autologous bone marrow in the reduction of scar tissue in the heart muscle and in the improvement of segmental contactile 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

Health condition(s) or problem(s) studied
Surgery: Coronary artery bypass grafting (CABG)

Interventions
[A] Control group receiving only myocardial revascularisation
[B] Direct injection into the scar muscle of self bone marrow mononuclear cells in addition to myocardial revascularisation
[C] Intravascular administration of self bone marrow into the graft used for myocardial revascularisation

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure

Functional improvement, and reduction in size of scar areas. The study will also establish whether the number and the type of transplanted bone marrow mononuclear cells is correlated with the recovery of contractile function by performing multiple linear regression analysis.

Secondary outcome measures
Not provided at time of registration

Overall study start date
07/04/2004

Completion date
07/04/2007

Eligibility

Key inclusion criteria
Patients undergoing coronary bypass graft surgery aged between 18 and 80. Estimated 30 patients per group in order to detect significance

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
80 Years

Sex
Not Specified

Target number of participants
Estimated 30 patients per group

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
07/04/2004

Date of final enrolment
07/04/2007

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Consultant Cardiologist
Birmingham
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Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
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Sponsor type
Government

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

Funder(s)

Funder type
Government

Funder Name
Good Hope Hospital 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	01/10/2008		Yes	No