

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/09/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 05/04/2011	Condition category Surgery	<input type="checkbox"/> 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

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

United Kingdom

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Sponsor information

Organisation

Department of Health

Sponsor details

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Sponsor type

Government

Website

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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