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Selected autologous bone marrow cell transplant following trans-mural myocardial infarction in patients undergoing coronary surgery: A prospective, double-blind, randomised controlled trial

Submission date 01/05/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 10/07/2008	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 04/04/2013	**Condition category** Circulatory System	[_] Individual participant data [_] Record updated in last year

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
Sponsor ref: CS/2005/2031

Study information

Scientific Title

Acronym
TransACT

Study objectives
The transplantation of bone marrow derived CD133+ autologous stem cells in and around large asynergic scarred areas of the heart will induce neoangiogenesis and neomyogenesis restoring local viability and contractility. CD133+ transplantation may also prevent left ventricular (LV) remodelling, improving mid-term quality of life in patients with ischemic non-dilated cardiomyopathy undergoing coronary surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NHS Southmead Research Ethics Committee (ref: 05/Q2002/50). Date of approval: 20/07/2005. Amendment approved on 06/08/2007.

Study design
Double-blind, randomised, placebo-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 the contact details provided in the Interventions field to request a patient information sheet.

Health condition(s) or problem(s) studied
Cardiac disease/ coronary surgery

Interventions

Experimental intervention: Injection of enriched autologous CD133+ stem cells derived from bone marrow, suspended in autologous plasma
Comparator intervention: Injection of autologous plasma

Please use the following contact details to request a patient information sheet:
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Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Regional LV thickening of the injected segments of the left ventricle 6 months after surgery measured by cardiac MRI. The use of MRI will also allow us to ascertain the reasons for any observed changes in wall thickening at the injected sites at 6 months by comparing the transmural distribution of viable myocardium and scar before and after surgery.

Secondary outcome measures
The following outcomes will be measured pre-operatively and at 6 months after surgery:
1. Scar distribution and the viability of the myocardium with MRI
2. LV segmental and global function with echocardiography
3. Mid-term generic and cardiac specific health status and quality of life. These will be assessed by the disease-specific Coronary Revascularisation Outcome Questionnaire, the Minnesota Living with Heart Failure Questionnaire and the 36-item Short Form health survey (SF-36)
4. Myocardial injury throughout the entire study period by measuring troponin I levels

Overall study start date
01/06/2008

Completion date
01/03/2011

Eligibility

Key inclusion criteria
1. Patients of either sex, aged 16 years or over and under 80 years
2. Recent (>10 days and 3 months) anterior ST-Segment Elevation Myocardial Infarction (STEMI) who have not undergone primary angioplasty
3. Cardiac magnetic resonance imaging (MRI) documented anterior myocardial infarction (MI) with a transmurality of >= 50% wall thickness in at least 1 segment of the LAD territory
4. Requirement for coronary artery bypass graft (CABG) alone to bypass stenoses or occlusions

of the left anterior descending artery (LAD) territory and any other territory as dictated by baseline coronary angiography
5. Absence of LV dilation (LV end systolic volume index <60 ml/m^2)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
60 (30 in each group)

Key exclusion criteria
1. Presence of cardiogenic shock or presence of acute left and/or right-sided pump failure as judged by the presence of pulmonary oedema and/or new peripheral oedema
2. Cardiac MRI documented MI transmurality of <50% wall thickness in all 7 segments of the LAD territory
3. Presence of LV dilatation (LV end systolic volume index >60 ml/m^2)
4. Cardiomyopathy secondary to a reversible cause
5. Known active infection
6. Chronic inflammatory disease
7. Serum creatinine >= 200 mmol/L
8. Contraindications for bone marrow aspiration
9. Female subjects of childbearing potential
10. Emergency operation for unstable angina
11. History of pace-maker or defibrillator insertion

Date of first enrolment
01/06/2008

Date of final enrolment
01/03/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Level 7, Research Floor
Bristol
United Kingdom
BS2 8HW

Sponsor information

Organisation
United Bristol Healthcare NHS Trust (UK)

Sponsor details
UBHT Research and Effectiveness Department
Bristol Royal Infirmary
Marlborough Street
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BS2 8HW
+44 (0)117 342 0233
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Sponsor type
Hospital/treatment centre

Website
http://www.ubht.nhs.uk

ROR
https://ror.org/04nm1cv11

Funder(s)

Funder type
Charity

Funder Name
British Heart Foundation (UK)

Alternative Name(s)
the_bhf, The British Heart Foundation, BHF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location

United Kingdom

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