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Bone-marrow derived stem cell transplantation in patients undergoing left ventricular restoration surgery for dilated ischaemic end-stage heart failure

Submission date
27/07/2009

Recruitment status
No longer recruiting

Registration date
14/10/2009

Overall study status
Completed

Last Edited
12/04/2017

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] 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
CS/2008/3027

Study information

Scientific Title
Bone-marrow derived stem cell transplantation in patients undergoing left ventricular restoration surgery for dilated ischaemic end-stage heart failure: a randomised blinded controlled trial

Acronym
TransACT 2

Study objectives
The aim of this study is to determine the effects of CD133+ autologous stem cells transplantation in and around asynergic non-viable left ventricular (LV) segments in patients with dilated ischaemic heart disease undergoing left ventricular reshaping surgery and coronary artery bypass graft (CABG).

Ethics approval required
Old ethics approval format

Ethics approval(s)
NHS Southmead Research Ethics Committee, 20/07/2005, ref: 05/K2002/49

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

Eligible patients undergoing SVR surgery will be allocated to either:
1. Intervention group: SVR surgery and transplantation of autologous CD133+
2. Control group: SVR surgery and injection of placebo, i.e. autologous plasma

Please use following contact details to request a patient information sheet:
Dr Jodi Taylor
Clinical Trials Co-ordinator
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Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Regional LV thickening of the 'affected' segments 6 months after surgery, i.e. end systolic thickness minus end diastolic thickness (millimetres). Affected segments will be those scored on the cardiac MRI taken 3 - 5 days after surgery, as 1 - 5 (dysfunctional) on a 5-point scale. Affected segments will be the segments which the surgeons aims to inject with stem cells or plasma. Measured at baseline (3 - 5 days post-operatively) and 6 months follow-up.

Secondary outcome measures
1. Mid-term generic and cardiac-specific health status and quality of life, measured at baseline and 6 months follow-up
2. End systolic volume and stroke volume quantified by cardiac MRI, measured at baseline (3 - 5 days post-operatively) and 6 months follow-up
3. Myocardial injury throughout the duration of the study by measuring troponin I levels (24 hours pre-operatively, surgery, 4, 12, 24 hours post-operatively, 6 weeks and 6 months follow-up)

Overall study start date
01/08/2009

Completion date
01/02/2012

Eligibility

Key inclusion criteria
1. Previous anterior myocardial infarction (with evidence of large surgically excludible scar at cardiac magnetic resonance imaging [MRI])
2. Significant LV dilation (left ventricular end-systolic volume index [LVESVI] greater than or equal to 60 ml/m^2
3. Left ventricular ejection fraction less than or equal to 35%
4. New York Heart Association (NYHA) class III/IV and one episode of congestive heart failure

(CHF) requiring medical attention
5. Elective left ventricular restoration surgery indicated
6. Elective CABG indicated to bypass stenoses or occlusions of coronary arteries
7. Patient aged 16 years or over and under 80 years old, either sex

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Severe acute renal failure requiring dialysis or serum creatinine greater than or equal to 200 mmol/L
2. Atrial fibrillation
3. Malignancy
4. Debilitating neurological disease
5. Emergency operation for unstable angina
6. Previous cardiac surgery/sternotomy
7. Concomitant valve procedures
8. History of significant ventricular arrhythmias
9. History of pacemaker and/or defibrillator insertion
10. Right ventricular (RV) failure
11. Pulmonary hypertension greater than 60 mmHg (angiogram or Elixis)
12. Known active infection
13. Chronic inflammatory disease
14. Contraindication for bone marrow aspiration
15. Female subjects of childbearing potential

Date of first enrolment
01/08/2009

Date of final enrolment
01/02/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Level 7, Research Floor
Bristol
United Kingdom
BS2 8HW

Sponsor information

Organisation
University Hospitals Bristol NHS Foundation Trust (UK)

Sponsor details
Research and Effectiveness Department
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Sponsor type
Hospital/treatment centre

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

ROR
https://ror.org/04nm1cv11

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Biomedical Research Unit

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