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Percutaneous Randomised Infusion of Marrow Aspirate To Improve Ventricular Efficiency

Submission date 31/05/2006	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 20/07/2006	**Overall study status** Stopped	
Last Edited 05/04/2013	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2006-003319-39

Protocol serial number
UHL 9981

Study information

Scientific Title

Acronym
The PRIMATIVE Study

Study objectives
Autologous bone-marrow derived stem cells delivered percutaneously to the damaged myocardium via the heart attack related artery can significantly improve left sided heart function after a heart attack without significant adverse effects.
This impact is evident even if the bone marrow cells are delivered late after the index event.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Leicestershire, Northamptonshire and Rutland Committee 1 on the 12th December 2006 (ref: 06/Q2502/58). EudraCT number: 2006-003319-39.

Study design
Randomised, double blind, interventional study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Coronary Heart Disease

Interventions
Status of trial amended to 'stopped' as of 05/04/2013 due to notification that it was not started.

The control group will receive a placebo stem cell transfusion made up of autologous heparinised plasma and the study group will receive autologous Stem Cell Therapy (SCT).

The following measurements will be made:
1. Coronary Angiogram
2. Four Magnetic Resonance Imaging (MRI) scans
3. Bone marrow cell aspiration
4. Stem cell transfusion
5. Holter monitoring
6. Atrial Natriuretic Peptide (ANP)/Brain Natriuretic Peptide (BNP) blood samples
7. Cardiac markers samples

Intervention Type
Other

Phase

Not Specified

Primary outcome(s)
Improvement in left ventricular function is determined by the comparison of the mean left ventricular EF in the stem cell treated and control groups, measured on initial MRI and that at four months in the early stem cell group and comparison of mean left ventricular EF measured at four months and one year in stem cell treated and control in the late treatment group. Maintenance of benefit will be assessed by comparison of EF at 12 months in subjects randomised to SCT in the early treatment group.

Key secondary outcome(s))
1. All cause and cardiac mortality at 12 months
2. Troponin and CK enzyme rise at 12 months post all interventional procedures
3. Hospitalisation for heart failure (symptoms of dyspnoea at minimal effort or at rest despite conventional treatment) at twelve months
4. Recurrent MI within 12 months
5. Need for revascularisation (exercise tolerance test positive)(PCI/CABG) to Target Lesion Revascularisation (TLR) and non-TLR at four and 12 months
6. Hospitalisation for arrythmias
7. Presence of malignant arrythmias (ventricular fibrillation, ventricular tachycardia, frequent ventricular ectopics) on 24 hour Electro cardiogram (ECG) monitoring at one, six and 12 months
8. ANP/BNP measured at baseline, four and 12 months
9. Inflammatory status (full blood leucocytes count and C-Reactive Protein performed pre- and post- SCT)
10. Scar size assessed by Gadolinum enhanced MRI scans in 50% each group

Completion date
01/07/2009

Reason abandoned (if study stopped)
Lack of staff/facilities/resources

Eligibility

Key inclusion criteria
1. Aged 18 - 80 years
2. Acute myocardial infarction with chest pain, ST segment elevation >0.2 mV in more than two contiguous leads, peak Creatine Kinase (CK) >600 U/l, for MB isoenzyme
3. First documented Acute Myocardial Infarction (AMI)
4. Referred for rescue Percutaneous Coronary Intervention (PCI)
5. Thrombolysis In Myocardial Infarction (TIMI) grade three flow in infarct related artery following PCI
5. Ejection Fraction (EF) less than 45% following standard treatment
6. No plans for additional revascularisation during the course of the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. TIMI grade zero or one flow despite intervention
2. Chronic inflammatory disease
3. Non-Infarct Related Artery (IRA) revascularisation likely over coming six months
4. Cerebral infarction within past year
5. More than 70% stenosis in non-IRA
6. Active infection (clinical/C-Reactive Protein (CRP)/White Blood Cells (WBC)/blood culture)
7. EF more than 45% following standard treatment
8. Known Human Immunodeficiency Virus (HIV) infection
9. Documented Previous Myocardial Infarction (MI)
10. Renal impairment (creatinine >180 mmol/l)
11. Previous Coronary Artery Bypass Graft (CABG)/PCI
12. Liver dysfunction (abnormal Liver Function Test or International Normalized Ratio (INR) >1.5)
13. Cardiogenic shock at presentation
14. Anaemia (haemaglobin less than 8.5 mg/dl)
15. History of neoplastic disease
16. Low platelet count (less than 100.000 µl)
17. History of hereditary bleeding disorder
18. History of gastro-intestinal bleeding within past three months
19. Major surgery/trauma within past two months
20. Women with childbearing potential
21. Arteriovenous Malformation (AVM)/aneurysms

Date of first enrolment
01/07/2006

Date of final enrolment
01/07/2009

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

Cardiology Department
Leicester
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LE3 9QP

Sponsor information

Organisation
University Hospitals of Leicester NHS Trust (UK)

ROR
https://ror.org/02fha3693

Funder(s)

Funder type
University/education

Funder Name
University Hospitals of Leicester NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration