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Randomised controlled trial to compare the effects of granulocyte-colony stimulating factor (G-CSF) and autologous bone marrow progenitor cells infusion on quality of life and left ventricular function in patients with heart failure secondary to ischaemic heart disease

Submission date
28/07/2005

Recruitment status
No longer recruiting

Registration date
23/11/2005

Overall study status
Completed

Last Edited
04/03/2013

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
1.2

Study information

Scientific Title

Acronym
REGENERATE-IHD

Study objectives
1. Administration of G-CSF to patients with heart failure secondary to ischaemic heart disease will lead to an increase in circulating progenitor cells as measured by peripheral CD34+ positive cell counts
2. Cardiac function and symptoms will improve in patients in whom the peripheral CD34+ counts increase in response to G-CSF administration
3. Direct coronary injection of autologous bone marrow derived stem cells will confer an additional improvement in cardiac function and symptoms above that derived from G-CSF infusion alone
4. Direct intramyocardial injection of autologous bone marrow derived stem cells will lead to an improvement in cardiac function and symptoms above that derived from G-CSF infusion alone

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)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Heart failure secondary to ischaemic heart disease.

Interventions
Daily subcutaneous injections of G-CSF at 10 µg/kg or placebo OR daily subcutaneous injections of G-CSF at 10 µg/kg followed by intracoronary injection of stem cells or placebo OR daily subcutaneous injections of G-CSF at 10 µg/kg followed by intramyocardial injection of stem cells or placebo

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
At 6 months:
1. The change in global left ventricular ejection fraction (LVEF) at 6 months relative to baseline measured by quantitative left ventriculography
2. The change in regional wall motion score index at 6 months relative to baseline measured by tissue doppler imaging
3. The change in quality of life scores compared to baseline

Secondary outcome measures
At 6 months:
1. Death as result of the underlying cardiac condition
2. The occurence of major arrhythmias defined as ventricular tachycardia or survived sudden death
3. Presence of clinically evident heart failure
4. The change in global left ventricular ejection fraction at 6 months relative to baseline measured by resting echocardiography
4. The change in global and regional wall motion score index measured by resting echocardiography
5. Serum levels of amino-terminal pro-brain natriuretic peptide (NT-BNP)
6. Change in myocardial function as measured by magnetic resonance imaging (MRI) scanning (first 40 suitable patients in each group)
7. Change in voltage and shortening maps as assessed by NOGA (intramyocardial group only)

At 12 months:
1. The occurrence of a major adverse cardiac event (MACE)
2. The change in left ventricular ejection fraction relative to baseline measured by resting echocardiography using Simpson's rule
3. The change in global and regional wall motion score index measured by resting echocardiography and tissue doppler imaging
4. Change in quality of life scores
5. Serum levels of amino-terminal pro-brain natriuretic peptide (NT-BNP)
5. Change in myocardial function as measured by MRI scanning (first 40 suitable patients in each group)

Overall study start date
18/05/2005

Completion date
18/05/2010

Eligibility

Key inclusion criteria
Patients with a diagnosis of heart failure secondary to ischaemic heart disease attending a heart failure clinic for optimisation of their heart failure medication or who are on optimal heart failure treatment under supervision from their physician.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
300

Key exclusion criteria
1. Recent acute coronary sydrome as judged by a rise of troponin above normal values in the last 6 months
2. The presence of cardiogenic shock
3. The presence of acute left and/or right-sided pump failure as judged by the presence of pulmonary oedema and/or new peripheral oedema
4. Known severe pre-existent left ventricular dysfunction (ejection fraction <10% prior to randomisation)
5. Congenital cardiac disease
6. Cardiomyopathy secondary to a reversible cause e.g. thyroid disease, alcohol abuse, hypophosphataemia, hypocalcaemia, cocaine abuse, selenium toxicity and chronic uncontrolled tachycardia
7. Cardiomyopathy in association with a neuromuscular disorder e.g. Duchenne's progressive muscular dystrophy
8. Contra-indication for bone marrow aspiration
9. Known active infection
10. Known infection with human immunodeficiency virus (HIV), hepatitis B virus (HBV), or hepatitis C virus (HCV)
11. Lifestyle with high risk for infection with HIV, HBV, or HCV
12. Chronic inflammatory disease
13. Serious known concomitant disease with a life expectancy of less than one year
14. Follow-up impossible (no fixed abode etc.)
15. Previous participation in this study
16. Female subjects of childbearing potential
17. Paced rhythm >80% of the time
18. Serum creatinine >200 mg/dl

Date of first enrolment

18/05/2005

Date of final enrolment
18/05/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The London Chest Hospital
London
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E2 9JX

Sponsor information

Organisation
Barts and the London NHS Trust (UK)

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.heartcellsfoundation.com

ROR
https://ror.org/00b31g692

Funder(s)

Funder type
Charity

Funder Name
The Heart Cells Foundation

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?
Interim results article	interim results	01/01/2009		Yes	No