

# 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

<b>Submission date</b> 28/07/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results <input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year
<b>Registration date</b> 23/11/2005	<b>Overall study status</b> Completed	
<b>Last Edited</b> 04/03/2013	<b>Condition category</b> Circulatory System	

**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 occurrence 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 syndrome 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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## **Sponsor information**

**Organisation**

Barts and the London NHS Trust (UK)

**Sponsor details**

The London Chest Hospital

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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?
<a href="#">Interim results article</a>	interim results	01/01/2009		Yes	No