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A Phase II, Open-label, Randomized, Multicenter Study to Assess the Safety and Cardiovascular Effects of Myocell™ Implantation by a Catheter Delivery System in Congestive Heart Failure Patients Post Myocardial Infarction(s)

Submission date 01/03/2006	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 10/03/2006	**Overall study status** Completed	
Last Edited 28/01/2019	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.bioheartinc.com

Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00375817

Secondary identifying numbers
BMI-EU-02-008

Study information

Scientific Title
A double-blind, randomized, controlled, multicenter study to assess the safety and cardiovascular effects of skeletal myoblast implantation by catheter delivery in patients with chronic heart failure after myocardial infarction

Acronym
SEISMIC

Study objectives
Is MyoCell™ treatment effective for improving patients cardiac function? (where cardiac function is assessed by a series of measurements indicating improvement or degradation of patients cardiovascular function, exercise capacity, frequency of hospitalizations (both positive and negative), the length of stay, mechanical function and functional status)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by the West Essex Local Research Ethics Committee (UK), 06/01/2006, reference number: 05/Q0301/46

Study design
Open-label, randomized, multicenter study

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
Ischemic cardiomyopathy (heart failure)

Interventions
Cell delivery via needle injection catheter versus standard medical therapy

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
MyoCell

Primary outcome measure
The primary safety objective defined for this study is as follows:
The MyoCell™ implant will be considered safe if the number of serious adverse events at three months and six months is less than that seen in the control group (receiving standard medical therapy), and falling within levels set in the statistical analysis plan. In addition, the number and mean length of stay for hospitalizations will also be captured.

Primary MyoCell™ efficacy objective:
The primary efficacy objective of SEISMIC is to demonstrate the response to MyoCell™ implantation on the change in Left Ventricular Systolic Function (LVEF) at three and six months by MUGA compared to baseline. Comparisons on LVEF will also be made between the two randomized groups (i.e. MyoCell™ implantation and standard medical therapy).

Secondary outcome measures
Secondary Efficacy Objectives:
The secondary efficacy objective will be defined in the statistical analysis plan and will include but not be limited to:
1. Six Minute Walk (6MW) distance, NYHA classification, average Quality of Life (QOL) score, hospitalization, readmissions or the need for medical treatment outside of hospitalizations
2. Contrast aided-dobutamine stress echo (using non-ionic contrast) and tissue doppler imaging for all patients to show improvements in:
a. Global and regional contractility
b. Wall thickness improvements
c. Coronary perfusion
d. A further optional objective will be to assess any changes in infarct size seen after three and six months, compared to baseline

Secondary Safety Objectives:
An additional safety objective will be to investigate the safety of the use of the MyoCath™, when used as a means of delivery of MyoCells™ for intracardiac implantation

Overall study start date
15/03/2006

Completion date
15/06/2006

Eligibility

Key inclusion criteria
1. Defined region of myocardial dysfunction related to previous myocardial infarction (most recent myocardial infarction must have occurred at least 90 days prior to muscle biopsy) involving the anterior, lateral, posterior or inferior walls, assessed by the presence of a Q-wave on the electrocardiogram (ECG) and a large area of akinesia in the left ventricle, confirmed by either left ventricular angiography or echocardiography
2. New York Heart Association (NYHA) symptom class II or III
3. Patients on optimal medical drug therapy for at least two months prior to study entry - defined as following the most current American College of Cardiology (ACC) or American Heart Association (AHA) guidelines for the evaluation and management of chronic heart failure in adults
4. Age ≥18 and ≤75 years old
5. Need or feasibility for re-vascularization has been ruled out by coronary angiogram or non-invasive stress testing within 30 days of screening, assessed using dobutamine stress echocardiography
6. Able to undergo surgical biopsy of the skeletal muscle and successful culture of the harvested myoblasts
7. Well demarcated transmural myocardial scar, assessed by echocardiography. Patients must have a minimum myocardial wall thickness of 5 mm.
8. Must have been fitted with an Implantable Cardioverter Defibrillator (ICD) in place for the duration of the study at least six months prior to muscle biopsy
9. Left ventricular ejection fraction at screening of ≥20% ≤45% (by multi-acquisition gated [MUGA] scan)
10. Willing and able to give written informed consent
11. If a female of childbearing potential, serum or urine pregnancy test must be negative within two weeks of study treatment

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
46 (30 treatment, 16 control)

Key exclusion criteria
1. Myocardial infarction within 90 days of the patients muscle biopsy
2. New York Heart Association Symptom Class I or IV

3. Coronary Artery Bypass Grafting (CABG) within six months (180 days) prior to scheduled MyoCell™ implantation
4. Percutaneous Coronary Intervention (PCI) within three months (90 days) prior to scheduled MyoCell™ implantation
5. Aortic valve replacement
6. Heart failure secondary to valvular disease
7. Left ventricular mural thrombus
8. Known sensitivity to gentamicin sulfate and/or amphotericin-B
9. Previous experimental angiogenic therapy and/or myocardial laser therapy
10. Previous severe adverse reaction to non-ionic radiocontrast agents
11. Exposure to any investigational drug or procedure within one month prior to study entry or enrolled in any concurrent study that may confound the results of this study
12. Serum creatinine >2.5 mg/dl or end stage renal disease
13. Active infectious disease and/or known to have tested positive for Human Immunodeficiency Virus (HIV), Human T-cell Lymphotropic Virus (HTLV), Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), Cytomegalovirus (CMV) (IgM > IgG) and/or syphilis. If the panel includes antibodies to the anti-hepatitis B virus core antigen (HBV-cAg) and anti-hepatitis B virus surface antigen (HBV-sAg), then an expert will be consulted as to patient eligibility based on the patients infectious status.
14. Females who are pregnant or nursing or females of childbearing potential who are unwilling to maintain contraceptive therapy for the duration of the study
15. Any illness which might affect patients survival over the study follow-up period or any illness which, in the investigators judgment, will interfere with the patients ability to comply with the protocol, compromise patient safety, or interfere with the interpretation of the study results
16. Patients on chronic immunosuppressive transplant therapy
17. ICDs implanted less than six months prior to cellular implantation procedure. ICD devices reprogrammed during the course of treatment and stable for less than three months. Patients fitted with a Bi-V pacer are excluded.

Date of first enrolment
15/03/2006

Date of final enrolment
15/06/2006

Locations

Countries of recruitment
Belgium

Germany

Netherlands

Poland

Spain

United Kingdom

United States of America

Study participating centre
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Sponsor type
Industry

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ROR
https://ror.org/03n30a589

Funder(s)

Funder type
Industry

Funder Name
Bioheart Inc. (USA)

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?
Results article	results	01/10/2011	28/01/2019	Yes	No