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Intra-coronary freshly isolated bone marrow cells transplantation improve cardiac function in patients with ischemic heart disease

Submission date
23/11/2011

Recruitment status
No longer recruiting

Registration date
23/12/2011

Overall study status
Completed

Last Edited
06/10/2016

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims:
Ischemic heart disease occurs when the heart's blood supply is blocked or interrupted by a build-up of fatty substances in the coronary arteries. The main symptoms are chest pain, heart attacks and heart failure. Cell therapy is a promising new treatment option. The aim of this study is to find out whether transplantation of a patient’s bone marrow stem cells into their heart has beneficial effects on their heart function.

Who can participate?
Patients aged 18 - 80 who have had a heart attack in the last 3 months

What does the study involve?
There are two groups of patients in this study. Both groups undergo coronary angiography, a test that uses dye and x rays to show the insides of the coronary arteries. One group receives cell therapy, while the other group does not receive cell therapy. Heart function is assessed at the start and 6 months later.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
University Hospital of Rostock (Germany)

When is the study starting and how long is it expected to run for?
February 2009 to June 2010

Who is funding the study?
University Hospital of Rostock (Germany)

Who is the main contact?
Dr R Gökmen Turan

Contact information

Type(s)
Scientific

Contact name
Dr R. Gökmen Turan

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2009/2

Study information

Scientific Title
Intra-coronary freshly isolated bone marrow cells transplantation improve cardiac function in patients with ischemic heart disease: a non-randomised study

Study objectives
In this study we analyzed whether intracoronary autologous freshly isolated bone marrow cells transplantation (BMCs-Tx) have beneficial effects on cardiac function in patients with ischemic heart disease (IHD)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee, University Rostock, Germany, 14/12/2008, ref: II PV 11/01

Study design
Non-randomized controlled study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Ischemic heart disease

Interventions
There are two groups, both groups underwent coronary angiography, first group received additional cell therapy, second group serve as control group received only coronary angiography without cell therapy.

Intervention Type
Procedure/Surgery

Primary outcome measure
The change in global ejection fraction (EF) as well as the size of infarcted area measured baseline and 6 months after coronary angiography in both groups.

Secondary outcome measures
The functional status by New York Heart Association (NYHA) classification and Brain natriuretic peptide (BNP) level in peripheral blood measured baseline and 6 months after coronary angiography in both groups.

Overall study start date
01/02/2009

Completion date
01/06/2010

Eligibility

Key inclusion criteria
1. Patients between 18-80 years of age
2. Had a documented myocardial infarction (MI) at least 3 months
3. Had a clear-cut demarcated region of the left ventricular dysfunction with and open infarct related coronary artery

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
80 Years

Sex
Both

Target number of participants
24

Key exclusion criteria
1. Presence of acutely decompensated heart failure with NYHA class of IV
2. Infectious or inflammatory disease
3. Active bleeding
4. Surgery or trauma within 2 months
5. Renal or liver dysfunction
6. Tthrombocytopenia or anemia
7. Alcohol or drug dependency
8. A history of other severe chronic diseases or cancer
9. Unwillingness to participate

Date of first enrolment
01/02/2009

Date of final enrolment
01/06/2010

Locations

Countries of recruitment
Germany

Study participating centre
Medical Faculty of the University of Rostock
Rostock
Germany
18057

Sponsor information

Organisation
University Hospital of Rostock (Universitätsklinikum Rostock) (Germany)

Sponsor details
Medical Faculty of the University of Rostock
Schillingallee 35
Rostock
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18057

Sponsor type
University/education

Website
http://www.med.uni-rostock.de/

ROR
https://ror.org/04dm1cm79

Funder(s)

Funder type
University/education

Funder Name
University Hospital of Rostock (Germany)

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	25/04/2012		Yes	No