

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/12/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 06/10/2016	Condition category Circulatory System	<input type="checkbox"/> 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

Contact details

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

80 years

Sex

All

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. Thrombocytopenia 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)

ROR

<https://ror.org/04dm1cm79>

Funder(s)

Funder type

University/education

Funder Name

University Hospital of Rostock (Germany)

Results and Publications

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