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Intra-coronary transfusion of autologous CD34+ cells improves left ventricular function in patients with diffuse coronary artery disease and non candidates for coronary artery intervention

Submission date
30/01/2012

Recruitment status
No longer recruiting

Registration date
17/02/2012

Overall study status
Completed

Last Edited
17/12/2020

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Coronary artery disease occurs when the heart's blood supply is blocked or interrupted by a build-up of fatty substances in the coronary arteries. Up to 20% of patients with severe coronary artery disease are unsuitable candidates for surgical treatment and also do not respond to medication. It is therefore important to finding a safe and effective alternative treatment for these patients. Stem cell therapy is the use of stem cells to treat or prevent a disease or condition. Recent studies have demonstrated that transfusion of CD34+ stem cells into the heart is safe and effective for improving heart dysfunction. The aim of this study is to test the safety, effectiveness and best dose of CD34+ cells in patients with severe coronary artery disease.

Who can participate?
Patients aged 20-80 with severe coronary artery disease who are not candidates for surgical treatment and do not respond to medication

What does the study involve?
All participants receive eight doses of G-CSF for 4 days, which makes some stem cells move from the bone marrow into the blood. The participants' CD34+ cells are collected using a machine through a tube inserted into a vein in the groin (femoral catheter) for 3-4 hours. After measuring the number of CD34+ cells, the CD34+ cells are delivered into the heart on the same day. The participants are randomly allocated to receive one of two doses of CD34+ cells through a tube into the heart (cardiac catheterization). Both groups also receive medical treatment as usual. The effectiveness and best dose are assessed and participants are monitored for any severe side effects during hospitalization and follow-up in the 1st week, 1st month, and every 3 months for one year after treatment.

What are the possible benefits and risks of participating?
The results of this study will provide important information about the effectiveness of stem cells for treating heart disease. Patients receive regular clinical follow-up one year and may benefit from early detection of heart failure. The possible risks include the risk during G-CSF injection (mainly bone soreness), during femoral catheter insertion (mainly hematoma [an abnormal collection of blood outside of a blood vessel]), during CD34+ cell collection (mainly muscle cramp due to low blood calcium), and during cardiac catheterization (death, heart rhythm problems, tear, blockage, infection and hematoma).

Where is the study run from?
Kaohsiung Chang Gung Memorial Hospital (Taiwan)

When is the study starting and how long is it expected to run for?
December 2011 to December 2014

Who is funding the study?
National Science Council (Taiwan)

Who is the main contact?
Dr Fan-Yen Lee

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Intra-coronary transfusion of autologous CD34+ cells improves left ventricular function in patients with diffuse coronary artery disease and non candidates for coronary artery intervention: a randomised controlled trial

Study objectives
It is reasonable to seek both the safety, feasibility and potential effects on parameters of improving left ventricular (LV) ischemia and function and clinical outcome of intra-coronary infusion of CD34+ cells for patients who have angina pectoris that resulted in severely and diffusely atherosclerotic-obstructive coronary artery disease (CAD) with refractory to optimal medication are not the candidates for both Percutaneous Coronary Intervention (PCI) or coronary artery bypass graft (CABG), especially in the age of donor shortage.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Institutional Review Committee on Human Research, Kaohsiung Chang Gung Memorial Hospital, 31/03/2011, ref: 99-3985A
2. Department of Health, Taiwan, 02/12/2011, ref: 1005056011

Study design
Prospective randomized double-blind trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

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
Chronic ischemic heart disease

Interventions
Intra-coronary delivery of autologous CD34+ cells are performed in our cardiac catheterization laboratory at day 5 during hospitalization. While one group will receive 1x107 CD34+ cells , the other group will receive 3x107 CD34+ cells. Both groups will receive medical treatment as usual. Follow-up duration is one year.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The safety of intra-coronary delivery of autologous CD34+ cells in patients with severely and diffusely atherosclerotic obstructive CAD who are not candidates for PCI and CABG and unsatisfactory medical treated result
Patients will be monitored for any severe adverse events (mortality, malignant arrhythmia, stroke, myocardial infarction and re-admission for congestive heart failure) during hospitalization and follow-up at OPD in the 1st week, 1st month, and per 3 months for one year after therapy.

Secondary outcome measures
1. The efficacy and optimal dose of autologous intra-coronary CD34+ cell therapy on improving degree of angina pectoris
2. Quality of Life - Short Form (SF-36)
3. LV Function
4. Clinical outcome in patients with severe-diffuse CAD
5. Degree of angina pectoris with Canadian Cardiovascular Society class II- IV angina

Measured at week one, 1, 3, 6, 9 and 12 months

Overall study start date
02/12/2011

Completion date
01/12/2014

Eligibility

Key inclusion criteria
1. Patients aged 20-80
2. Have angina pectoris resulted in severely and diffusely atherosclerotic-obstructive CAD with refractory to optimal medication not the candidates for both PCI or CABG

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
40

Total final enrolment
38

Key exclusion criteria
1. Age <20 years or > 80 years
2. Pregnant women
3. Patients with adventitious agents [like:Human immunodeficiency virus (HIV), Hepatitis viruses]
4. Recent myocardial infarction (MI) within 3 months
5. Aortic stenosis or mitral stenosis
6. Congestive heart failure
7. New York Heart Association Functional Class IV (NYHA Fc.IV)
8. Malignancy or other severe disease with life span less than one year
9. Chronic kidney disease with creatinine clearance (CCr) <20ml/min and end stage renal disease

Date of first enrolment
02/12/2011

Date of final enrolment
01/12/2014

Locations

Countries of recruitment
Taiwan

Study participating centre
123, Ta Pei Road
Kaohsiung
Taiwan
83301

Sponsor information

Organisation
National Science Council (Taiwan)

Sponsor details
No.106, HoPing East Road
Sec. 2
Taipei
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10622

Sponsor type
Government

Website
http://web1.nsc.gov.tw/

ROR
https://ror.org/02kv4zf79

Funder(s)

Funder type
Government

Funder Name
National Science Council (Taiwan) ref: 100-2314-B-182A-077

Alternative Name(s)
National Science Council, Taiwan, National Science Council of Taiwan, NSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Taiwan

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	01/10/2015	17/12/2020	Yes	No
Results article	results	29/07/2020	17/12/2020	Yes	No