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

Submission date
12/08/2013

Recruitment status
No longer recruiting

Registration date
11/09/2013

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
Despite state-of-the-art treatment, including medications, use of improved devices and techniques, and an increase in experience of coronary artery interventions, up to 20% of patients who have severely and diffusely atherosclerotic obstructive coronary artery disease (CAD) are not only unsuitable candidates for coronary artery intervention (i.e., either percutaneous coronary artery intervention [PCI] or coronary artery bypass grafting [CABG]) but also have an ineffective response to optimal medication. Therefore, finding a safe and effective alternative treatment for these patients is important. Stem cell therapy has been established as an attractive and promising treatment for improving various ischemia (decrease in blood supply) related organ dysfunctions, including the heart and vascular system. Additionally, some recent studies have demonstrated that intra-coronary transfusion (injection given directly into the heart) of CD34+ cells is safe and effective for improving ischemia-related left ventricular (LV) dysfunction. Surprisingly, no data has been reported regarding stem cell therapy for CAD patients in Taiwan. Besides, there has been no reported data to address the issue of whether intracoronary transfusion of CD34+ cells is an alternative treatment strategy for severely and diffusely atherosclerotic obstructive CAD patients worldwide. The aim of this study is to investigate the safety and effectiveness of intra-coronary delivery of CD34+ cells.

Who can participate?
Patients aged 20-80 years with severely and diffusely atherosclerotic obstructive CAD who are not candidates for PCI and CABG and with unsatisfactory results from other medical treatment.

What does the study involve?
The participants are randomly allocated to one of two groups. The study group receives intra-coronary transfusion of CD34+ cells into the diffusely atherosclerotic blood vessel. The control group receives optimal medical therapy.

What are the possible benefits and risks of participating?
The possible benefits are improvement of cardiac function and quality of life. The risks include arrhythmia, increased risk of angina or heart failure, stroke, claudication (pain in the legs due to reduced blood flow), hemorrhage, anemia, renal insufficiency (kidney failure) and electrolyte imbalance.

Where is the study run from?
Taiwan

When is the study starting and how long is it expected to run for?
The study started in January 2013 and it is expected to run for 3 years.

Who is funding the study?
National Science Council Taiwan, Republic of China.

Who is the main contact?
Dr Hon-Kan Yip

Contact information

Type(s)
Scientific

Contact name
Dr Hon-Kan Yip

Contact details
123, Ta Pei Road
Niao Sung District
Kaohsiung
Taiwan
83302

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 randomized placebo controlled trial

Study objectives
It is reasonable to seek both the safety and feasibility and potential effects on parameters of improving left ventricular (LV) ischemia and function and clinical outcome of intracoronary infusion of CD34+ cells for patients who have angina pectoris due to severely and diffusely atherosclerotic obstructive CAD and are refractory to optimal medication who are not the candidates for both percutaneous coronary intervention (PCI) or coronary artery bypass graft (CABG).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Chang Gung Memorial Hospital 101-4261C

Study design
Prospective randomized placebo controlled 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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Chronic ischemic heart disease

Interventions
Intervention: autologous endothelial progenitor cells (5x10^7)
Control: optimal medical therapy

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure

The safety of intracoronary 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. Clinical follow-up (1 week, 1 month, 3 months, 6 months, 9 months, 12 months).

Secondary outcome measures
1. The efficacy of autologous intracoronary CD34+ cell therapy on improving degree of Angina Pectoris.
2. Quality of Life
3. LV function
4. Clinical Outcome in patients with severediffuse CAD

Methods and time points:
1. Canadian Cardiovascular Society Angina Class and New York Heart Association functional class: 1 week, 1 month, 3 months, 6 months, 9 months, 12 months.
2. Electrocardiogram: per day during hospitalization, 1 week, 1 month, 3 months, 6 months, 9 months, 12 months.
3. Echocardiography: 1 month, 3months, 6months.
4. Tl-201: 6 months.
5. Cardiac MRI: 6 months and 12 months.

Overall study start date
01/01/2013

Completion date
31/12/2015

Eligibility

Key inclusion criteria
Patients with age between 20-80 years-old who have angina pectoris resulted in severely and diffusely atherosclerotic obstructive CAD with refractory to optimal medication are not the candidates for both PCI or CABG

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
60

Total final enrolment
60

Key exclusion criteria
1. Age less than 20 years or more than 80 years
2. Pregnant women
3. Patients with adventitious agents (like HIV, Hepatitis viruses)
4. Myocardial infarction (MI) within 3 months
5. Aortic stenosis or mitral stenosis
6. Congestive heart failure, New York Heart Association functional class (NYHA Fc.)IV
7. Malignancy or other severe disease with life span less than one year
8. Chronic kidney disease with CCr<20ml/min and end stage renal disease

Date of first enrolment
01/01/2013

Date of final enrolment
31/12/2015

Locations

Countries of recruitment
Taiwan

Study participating centre
123, Ta Pei Road
Kaohsiung
Taiwan
83302

Sponsor information

Organisation
National Science Council (Taiwan)

Sponsor details
No. 106
HoPing E. Road
Sec.2
Taipei
Taiwan
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, Republic of China (grant no:102-2325-B-182A-012) (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		Yes	No
Results article	results	07/04/2020	15/04/2020	Yes	No
Results article	results	29/07/2020	17/12/2020	Yes	No