

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

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| Submission date 12/08/2013 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 11/09/2013 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 17/12/2020 | Condition category Circulatory System | <input type="checkbox"/> 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

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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 (5×10^7)

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 severe diffuse 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, 3 months, 6 months.
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 |