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Intra-coronary administration of tacrolimus prior to primary coronary intervention attenuates infarct size and improves left ventricular function in patients with ST-segment Elevation Myocardial Infarction

Submission date	**Recruitment status**	[ ] Prospectively registered
19/08/2013	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
11/09/2013	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
08/04/2016	Circulatory System	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims

Studies have previously shown that cyclosporine therapy effectively reduced left ventricular infarction size and preserved left ventricular function after acute myocardial infarction (heart attack). In view of the fact that immune and inflammatory reactions are one of the major contributors to death of the cells that make up the cardiac muscle (cardiomyocytes) after acute myocardial infarction and that the drug tacrolimus is more effective than cyclosporine, we think that tacrolimus may limit the extent of myocardial infarction and improve left ventricular function after heart attack. To test this idea, animal studies were conducted which showed promising results, raising the need for a study to investigate the impact of tacrolimus when given as an injection directly into the heart on improving reperfusion rate, left ventricular function and clinical outcome in patients with ST-segment elevation myocardial infarction undergoing primary percutaneous coronary intervention.

Who can participate?

Men and women, aged between 20 and 80 years old, with acute ST-segment elevation myocardial infarction occurring within 12 hours and receiving primary percutaneous coronary intervention (PCI).

What does the study involve?

The participants are randomly allocated to one of the two groups. In the study group, tacrolimus is injected directly into the heart before primary PCI. In the control group, normal saline is injected directly into the heart before primary PCI.

What are the possible benefits and risks of participating?
The possible benefits are improvement of heart function and reduction of adverse outcomes. Possible risks include reduced kidney function, neurotoxicity (affecting brain cells), hyperglycemia (increased blood sugar level) and diarrhoea.

Where is the study run from?
Six medical centres located in China and Taiwan.

When is the study starting and how long is it expected to run for?
The study started in September 2013 and it is expected to run for 4 years. The trial will be recruiting participants for 3 years, and all patients will be followed up at least 1 year.

Who is funding the study?
Chang Gung Memorial Hospital (Taiwan).

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
833

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Intra-COronary Administration of Tacrolimus prior to first-balloon attenuates infarct size and improves left ventricular function in patients with ST-segment Elevation Myocardial Infarction (COAT-STEMI) undergoing primary coronary intervention: a double-blind, placebo-controlled, randomized, multi-center clinical trial

Study objectives
Tacrolimus may limit the extent of myocardial infarction and improve left ventricular function in the setting of acute myocardial infarction.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Chang Gung Memorial Hospital, 29/07/2013, ref: 102-1228A3

Study design
Prospective randomized double blind 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: Hon-Kan Yip/ Chang Gung Memorial Hospital. E-mail: han.gung@msa.hinet.net

Health condition(s) or problem(s) studied
Acute ST segment elevation myocardial infarction

Interventions
Study arm- 600 participants. Intra-coronary transfusion of tacrolimus before primary percutaneous coronary intervention for acute myocardial infarction.
Control arm-600 participants. Intra-coronary transfusion of normal saline before primary percutaneous coronary intervention acute myocardial infarction.
The primary percutaneous coronary intervention procedures are the same in both arms and following the clinical practice. The duration of treatment is the same as the procedure of primary percutaneous coronary intervention. All patients will be followed up at least one year.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Percentage of Thrombolysis In Myocardial Infarction (TIMI)-3 flow post primary percutaneous coronary intervention after the procedure by coronary angiography (the same day).

Secondary outcome measures
1. 30 days mortality
2. One year cardiac mortality
3. One year adverse outcome (including mortality, reinfarction and target vessel revascularization)
4. One year re-hospitalization due to congestive heart failure
5. 6 months improvement of left ventricular function by echocardiography

Overall study start date
01/09/2013

Completion date
31/08/2016

Eligibility

Key inclusion criteria
Male and female, age between 20 and 80 years old with acute ST segment elevation myocardial infarction occuring less than 12 hours and receiving primary percutaneous coronary intervention (PCI).

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
1200

Key exclusion criteria
1. Recent myocardial infarction and stroke within 3 months
2. Receiving immunosupressant, adverse drug reaction for immunosuppressant, cardiogenic shock, active inflammative or infectious disease
3. Pregnant or breast feeding women
4. Liver cirrhosis
5. Hemodialysis patients
6. Patients receiving organ transplant
7. Malignancy
8. Life span less than 1 year

Date of first enrolment
01/09/2013

Date of final enrolment
31/08/2016

Locations

Countries of recruitment
China

Taiwan

Study participating centre
Kaohsiung Chang Gung Memorial Hospital
No.123, DAPI Road
Niaosng District
Kaohsiung City
Taiwan
83301

Study participating centre
Pingtung Christian Hospital
No. 60, Dalian Rdoad
Pingtung City
Taiwan
90

Study participating centre
Kaohsiung University Chung-ho Memorial Hospital
No. 100, Ziyou 1st Road
Sanmin District
Kaohsiung City
Taiwan
807

Study participating centre
Kaohsiung Veterans General Hospital
No. 386, Dazhong 1st Road
Zuoying District
Kaohsiung City
Taiwan
813

Study participating centre
Chi Mei Hospital
No.201, Taikang
Taikang Vil.
Liuying District
Tainan City
Taiwan
376

Study participating centre
Xiamen Cardiovascular Hospital
Medical College of Xiamen University
Xiamen
China
-

Sponsor information

Organisation
Chang Gung Memorial Hospital (Taiwan)

Sponsor details
123, Ta Pei Road
Niao Sung District
Kaohsiung
Taiwan
833

Sponsor type
Hospital/treatment centre

Website
http://www.cgmh.org.tw

ROR
https://ror.org/02verss31

Funder(s)

Funder type

Hospital/treatment centre

Funder Name
Chang Gung Memorial Hospital (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