

# 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

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<b>Registration date</b> 11/09/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 08/04/2016	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

### Protocol serial number

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

**Study type(s)**

Treatment

**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(s)**

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

**Key secondary outcome(s)**

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

**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 occurring less than 12 hours and receiving primary percutaneous coronary intervention (PCI).

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Key exclusion criteria**

1. Recent myocardial infarction and stroke within 3 months
2. Receiving immunosuppressant, adverse drug reaction for immunosuppressant, cardiogenic shock, active inflammatory 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  
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# Sponsor information

## Organisation

Chang Gung Memorial Hospital (Taiwan)

## ROR

<https://ror.org/02verss31>

# Funder(s)

## Funder type

Hospital/treatment centre

## Funder Name

Chang Gung Memorial Hospital (Taiwan)

# Results and Publications

Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration