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Study on connective tissue growth factor expressed in patients with ST-segment elevation myocardial infarction

Submission date 10/08/2015	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 31/08/2015	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 20/08/2015	**Condition category** Circulatory System	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Connective tissue growth factor (CTGF) is a protein which helps to make connective tissue, which connects, supports, binds, or separates other tissues or organs in the body. It has been found that CTGF can contribute to the thickening and stiffening of the heart valves. This can lead to conditions such as unstable angina (UA), a type of chest pain caused by poor blood flow to the heart which can lead to a heart attack, and ST-segment elevation myocardial infarction (STEMI), which is a type of heart attack. When a person has a heart attack, an enzyme called creatine kinase MB (CK-MB) is released into the blood by the injured heart muscle.
The aim of this study is to find out whether there is a link between the amount of CTGF in the body and the size of a heart attack. The study also aims to find out if the levels of CTGF relate to the levels of the CK-MB in STEMI patients.

Who can participate?
Adults suffering from sudden STEMI or UA.

What does the study involve?
Participants with UA have a blood test when they are admitted to hospital to test the level of CTGF in their blood. For participants who are suffering from STEMI, a sample of blood is taken 24 hours, 2 days, 7 days and 14 days after the heart attack itself. Blood is also taken every two hours in order to test for CK-MB, and to work out the when the levels in the blood are at their highest.

What are the possible benefits and risks of participating?
There are no notable benefits or risks for the participants.

Where is the study run from?
The Second Affiliated Hospital of Xuzhou Medical College (China)

When is the study starting and how long is it expected to run for?
July 2013 to March 2015

Who is funding the study?
The Second Affiliated Hospital of Xuzhou Medical College (China)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title
Connective Tissue Growth Factor was significantly expressed in ST-segment elevation Myocardial Infarction patients

Acronym
CTGFMI

Study objectives
To determine whether connective tissue growth factor assessment is a good index of the infarction size.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Second Affiliated Hospital of Xuzhou Medical College Ethics Committee, 25/06/2013, ref: SMC1306-25.

Primary study design
Observational

Study design
Observational cohort study

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
1. ST-segment elevation myocardial infarction
2. Angina

Interventions
All the patients received conventional intensive medical treatment and elective PCI after hospitalization. The door-to-balloon time was 278.3±43.2hours for these 94 patients from chest pain to infarction-related artery .Patients with myocardial infarction were extracted 5ml of venous blood to detect CTGF 24h, 2 days, 7 days, 14 days after disease onset respectively. Patients with UA were extracted 5ml of venous blood to detect CTGF at the time of hospitalization. Patients with STEMI were extracted 5ml of venous blood every two hours to detect CKMB and to obtain CKMB enzyme peak value.

Intervention Type
Device

Primary outcome(s)
The serum level of connective tissue growth factor (CTGF) and Creatine kinase-MB (CKMB) maximal value.

Key secondary outcome(s)
1. Ventricular ejection fraction.
2. Mortality Rate.

Completion date
15/04/2015

Eligibility

Key inclusion criteria
Suffering from one of the following:
1. Acute ST elevation myocardial infarction without direct PCI
2. Thrombolytic indications
3. Unstable angina

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Previous severe valvular disease
2. Cardiomyopathy
3. Severe chronic heart failure
4. Persistent atrial fibrillation.

Date of first enrolment
03/07/2013

Date of final enrolment
10/03/2015

Locations

Countries of recruitment
China

Study participating centre
The second affiliated hospital of Xuzhou Medical College
32 Meijian Road
Quanshan District
Xuzhou
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221006

Sponsor information

Organisation
The second affiliated hospital of Xuzhou Medical College

ROR
https://ror.org/04yrcjm56

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
The Second Affiliated Hospital of Xuzhou Medical College

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available