

# Adverse outcome post acute coronary syndrome in diabetes

<b>Submission date</b> 16/01/2017	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 20/01/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 07/04/2017	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Acute coronary syndrome (ACS) refers to a group of conditions due to decreased blood flow in the coronary arteries such that part of the heart muscle is unable to function properly or dies. It encompasses a range of sudden heart conditions, including heart attack and unstable angina attack (sudden chest pain). ACS mainly happens due to narrowing of the blood vessels which supply the heart due to a build-up of plaque (a fatty, sticky substance) on the walls of arteries. Treatment for ACS can include surgery to unblock the blood vessels to supply the heart and use of blood thinning medications. Patients who have type 2 diabetes (a condition where the sufferer is unable to control their blood sugar levels properly) are known to have a higher rate of complications than previously healthy patients. Previous studies have shown that a protein called pregnancy-associated plasma protein-A (PAPP-A) is a potentially important biomarker (natural indicator) of dangerous plaque and inflammation (swelling) in patients with ACS and has been identified in heart plaque. Patients with type 2 diabetes appeared to have high levels of PAPP-A than healthy people of the same age. The aim of this study is to find out whether increased levels of PAPP-A are an indicator of future heart and blood vessel complications after ACS.

### Who can participate?

All patients who have been hospitalised for ACS who have had their PAPP-A levels measured.

### What does the study involve?

After being admitted to hospital for ACS, participants are treated by cardiologists (heart doctors) as usual, following standard ACS treatment guidelines. Participants attend follow up appointments after 6, 12 and 24 months, where they are interviewed to find out if they have had any heart and blood vessel complications, such as stroke or heart attacks. This is then confirmed by reviewing medical records.

### What are the possible benefits and risks of participating?

There are no direct benefits or risks involved to those participating.

### Where is the study run from?

The Beijing Friendship Hospital Cardiovascular Center, Capital Medical University (China)

When is the study starting and how long is it expected to run for?  
June 2012 to December 2014

Who is funding the study?  
Chinese National Science Foundation (China)

Who is the main contact?  
Professor Xue-Qiao Zhao  
xueqiao@uw.edu

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**Protocol serial number**  
Chinese National Science Foundation (Grant No 81300161)

## Study information

**Scientific Title**  
Pregnancy-associated plasma protein-A is a stronger predictor for adverse cardiovascular outcomes post-acute coronary syndrome in patients with type 2 diabetes mellitus

**Study objectives**  
Pregnancy-associated plasma protein-A (PAPP-A) is predictive for future adverse cardiovascular outcomes in patients with type-2 diabetes (T2DM).

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**

Beijing Friendship Hospital Institutional Review Board, 01/04/2012

**Study design**

Observational study.

**Primary study design**

Observational

**Study type(s)**

Diagnostic

**Health condition(s) or problem(s) studied**

1. Acute coronary syndrome
2. Type-2 diabetes mellitus (T2DM)

**Interventions**

All study participants are enrolled into the study during their ACS hospitalization. During hospitalisation, participants are treated using standard techniques. This may include percutaneous coronary intervention (PCI), coronary artery bypass grafting (CABG) and medication, as decided by treating cardiologists following ACS treatment guidelines.

After hospital discharge, study participants are followed by their cardiologists for 24 months. After 6, 12 and 24 months, participants attend follow up visits at which the cardiovascular event rate is recorded.

**Intervention Type**

Other

**Primary outcome(s)**

1. Cardiovascular death rate is assessed by medical record review and confirmed with death certificate at baseline, 6, 12 and 24 months of the 2 years of follow-up
2. Non-fatal MI rate is assessed by patient interview and confirmed by medical record review at baseline, 6, 12 and 24 months of the 2 years of follow-up
3. Non-fatal stroke rate is assessed by patient interview and confirmed by medical record review at baseline, 6, 12 and 24 months of the 2 years of follow-up

**Key secondary outcome(s))**

No secondary outcome measures.

**Completion date**

30/12/2014

**Eligibility****Key inclusion criteria**

1. Confirmed acute coronary syndrome
2. Has PAPP-A measurements

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

All

**Sex**

All

**Key exclusion criteria**

1. Aystemic inflammatory disease or cancer
2. Missing PAPP-A measurements

**Date of first enrolment**

15/06/2012

**Date of final enrolment**

30/11/2012

## Locations

**Countries of recruitment**

China

**Study participating centre**

The Beijing Friendship Hospital Cardiovascular Center, Capital Medical University

95th Yongan Road

Xicheng District

Beijing

China

10050

## Sponsor information

**Organisation**

Chinese National Science Foundation

**ROR**

<https://ror.org/01h0zpd94>

## Funder(s)

**Funder type**  
Government

**Funder Name**  
National Natural Science Foundation of China

**Alternative Name(s)**  
Chinese National Science Foundation, Natural Science Foundation of China, National Science Foundation of China, NNSF of China, NSF of China, National Nature Science Foundation of China, Guójiā Zìrán Kēxué Jījīn Wěiyuánhùi, , NSFC, NNSF, NNSFC

**Funding Body Type**  
Government organisation

**Funding Body Subtype**  
National government

**Location**  
China

## Results and Publications

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Moni Blazej Neradilek (moni@mwlight.com)

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	05/04/2017		Yes	No