

Adverse outcome post acute coronary syndrome in diabetes

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

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Longitudinal study

Study setting(s)

Hospital

Study type(s)

Diagnostic

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

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 measure

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

Secondary outcome measures

No secondary outcome measures.

Overall study start date

15/06/2012

Completion date

30/12/2014

Eligibility

Key inclusion criteria

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

Participant type(s)

Patient

Age group

All

Sex

Both

Target number of participants

420

Key exclusion criteria

1. Aysystemic 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

Sponsor details

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Sponsor type

Government

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

Publication and dissemination plan

Plans to public study results in the first quarter of 2017.

Intention to publish date

31/03/2017

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?
Results article	results	05/04/2017		Yes	No