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Adverse outcome post acute coronary syndrome in diabetes

Submission date
16/01/2017

Recruitment status
No longer recruiting

Registration date
20/01/2017

Overall study status
Completed

Last Edited
07/04/2017

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 he 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 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

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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 hosptialisation, 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 Wěiyuánhuì, , 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?
Results article	results	05/04/2017		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes