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Copeptin a marker for diagnosis and prognosis in heart attack

Submission date	Recruitment status	[_] Prospectively registered
29/07/2015	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
09/08/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
05/09/2023	Circulatory System	

Plain English summary of protocol

Background and study aims
Chest pain can be caused by a variety of conditions, some of them dangerous (such as a heart attack), others harmless (such as a muscle pain). The aim of the study is to show if a new marker (a protein measured in the blood) Copeptin, may be helpful in quickly identifying patients at higher risk for having a heart attack, thus enabling quick introduction of adequate treatment.

Who can participate?
Adult experiencing chest pain lasting five minutes or more within the last 6 hours.

What does the study involve?
Copeptin is measured for all participants via a blood test on admission to hospital. They then undergo routine treatment according to current guidelines and standards of care. Participants' follow-up data are collected and analyzed in regard to Copeptin concentrations.

What are the possible benefits and risks of participating?
The marker is measured from a blood sample which is taken at the same time as a standard blood test, so does not need additional puncture if the vein. Thus, the risk for participation in the study is minimal.

Where is the study run from?
2nd Department of Cardiology, Medical University of Silesia (Poland)

When is the study starting and how long is it expected to run for?
December 2011 to December 2018

Who is funding the study?
Silesian Medical University (Poland)

Who is the main contact?
Miss Beata Morawiec

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
COPeptin for diagnosis and prediction in acute coronary syndrome (COPACS) study: design and objectives

Acronym
COPACS - COPeptin for Acute Coronary Syndrome

Study objectives
Copeptin, the C-terminal part of prohormone for vasopressin, is a marker of acute endogenous stress. An immediate increase in concentration after a few minutes from the onset of chest pain and rapid peak of concentration (1-2h) have practical implications for chest pain patients. Together with cardiac troponin, which is a specific marker for myocardial injury, it could be effective in quickly identifying patients at higher risk for having a heart attack, thus enabling quick introduction of adequate treatment. The aim of this study is to see whether this is the case.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Committee of Medical University of Silesia, 06/12/2011, ref: KNW/0022/KB1/187/11

Study design
Prospective, observational single-center study

Primary study design
Observational

Secondary study design
Case series

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Chest pain

Interventions
Copeptin is measured in patients with chest pain lasting up to 6h at admission and remains double-blinded throughout the enrollment. Further all patients undergo routine management for the condition being the cause of admission, according to current guidelines and standards of care. Patients' follow-up data are collected and analyzed in regard to copeptin concentrations.

Intervention Type
Other

Primary outcome measure
1. Primary diagnostic endpoint is the final diagnosis of NSTEMI
2. Primary prognostic endpoint is death of cardiovascular origin

Secondary outcome measures
1. Secondary diagnostic endpoint is the diagnosis of ACS (NSTEMI+UA)
2. Secondary prognostic endpoints is as Major Adverse Cardiac and Cerebrovascular Events (MACCE) and included death of cardiovascular origin, non-fatal AMI, UA, repeated cardiac revascularization, stroke

Overall study start date
15/12/2011

Completion date
31/12/2018

Eligibility

Key inclusion criteria
1. Chest pain lasting five minutes or more
2. Beginning of symptoms in last six hours before admission

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
192 per first round of recruitment; up to 500 at the end of recruitment.

Total final enrolment
154

Key exclusion criteria
1. ST-segment elevation myocardial infarction (STEMI)
2. End-stage renal insufficiency (defined as GFR <15 ml/min/1.73m2 and/or dialysis)
3. Anemia (defined as level of hemoglobin <10 g/dl for men; <8 g/dl for women)
4. Hyponatremia (defined as level of Na+ <125mmol/l)
5. Injury or big surgery in last four weeks
6. Cancer with predicted life duration < six months
7. Pregnancy
8. Age < 18 years
9. Lack of informed consent

Date of first enrolment
15/12/2011

Date of final enrolment
31/12/2016

Locations

Countries of recruitment
Poland

Study participating centre
2nd Department of Cardiology, Medical University of Silesia
M. Sklodowskiej-Curie Str. 10

Zabrze
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41-800

Sponsor information

Organisation
Silesian Medical University

Sponsor details
Poniatowskiego Str 15
Katowice
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40-055

Sponsor type
University/education

ROR
https://ror.org/005k7hp45

Funder(s)

Funder type
University/education

Funder Name
Silesian Medical University (Poland)

Results and Publications

Publication and dissemination plan
First publication is planned to cover the design and objectives of the study and to be published in an international journal soon. Further plans to be confirmed at a later date.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	24/01/2018	11/12/2020	Yes	No
Other publications	Study design	17/11/2016	05/09/2023	Yes	No
Results article		12/11/2018	05/09/2023	Yes	No