Diagnostic value of signs, symptoms and Heart-type Fatty Acid-Binding Protein (H-FABP) in evaluating patients presenting with symptoms possibly matching acute coronary syndrome in primary care

Published: 28-08-2013
Last updated: 24-04-2024

To determine the added value of signs, symptoms and H-FABP measurement in in- or excluding acute coronary syndrome in patients with thoracic complaints in general practice

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Coronary artery disorders
Study type	Observational invasive

Summary

ID

NL-OMON43744

Source
ToetsingOnline

Brief title
RAPIDA - RAPid test for Investigating complaints possibly Due to ACS

Condition

- Coronary artery disorders

Synonym
acute coronary syndrome, heart infarction

Research involving
Human

Sponsors and support

Primary sponsor: Maastricht University dpt Huisartsgeneeskunde
Source(s) of monetary or material Support: FABPulous BV

Intervention

Keyword: acute coronary syndrome, diagnostic study, heart-type fatty acid binding protein, point of care test

Outcome measures

Primary outcome

Sensitivity, specificity, positive and negative predictive value for AMI of

H-FABP, alone as well as in combination with signs and symptoms, in patients

with thoracic complaints in primary care on initial consultation of their GP.

Determination of signs and symptoms that have additional value and therefore

can be used in the above mentioned algorithm to predict outcome, using

multivariate analysis of our data.

To determine influence of sex (male or female) and kidney function on

reliability of H-FABP-testing, subgroup analysis within our study population

will be performed. Subgroups on kidney function will consist of three groups of

eGFR, calculated with the commonly used mdrd-formula: eGFR < 15, eGFR 15-30,

eGFR 30-45, eGFR 45-60 and eGFR above 60 ml/min/1,73m2. Primary outcome will

be determined in each subgroup

Influence of time from onset of complaints to consultation of the GP (patient

delay and doctor's delay) on the primary outcome-values will be measured.

Secondary outcome

Cost-effectiveness of working with a PoC H-FABP-test will be calculated.

Determination of predictive value of a diagnostic algorithm towards diagnosing

UA, since UA is a condition without rise in biomarkers

Study description

Background summary

Thoracic complaints in general practice are only in a minority of cases of cardiac origin but to excluse cardiac origin during first presentation of symptoms is challenging. This causes significant referral of patients to coronary care units, where in the end, cardiac analysis turns out to be negative. On the other hand, because not all patients can reasonably be referred when suspicion of a cardiac cause is low, a cardiac cause of complaints can be missed

Study objective

To determine the added value of signs, symptoms and H-FABP measurement in in- or excluding acute coronary syndrome in patients with thoracic complaints in general practice

Study design

Eligible patients will be asked by the GP to participate. Diagnostic assessment during the initial consultation with the GP will take place with standardized history taking and physical examination, to be documented by the GP on the standardized case report form (appendix 1 included with this study protocol). Additionally, patient delay (time between onset of symptoms and contacting the GP office) and GP delay (time between initial (phone) contact to GP's office and physical presentation of patient to GP) are recorded. When available, electrocardiography is performed and a copy of the ECG is added to the case report form. Diagnostic interpretation can be done following the Dutch guideline on ACS, which GPs are familiar with6.

The decision by the GP whether or not referral to the cardiologist will take

place will be based on information obtained by history taking, physical examination and, when available and relevant, ECG only. The GP will be asked to decide whether or not to refer to a cardiologist and fill out this decision together with the presumptive diagnosis (e.g. ACS, pyrosis due to gastric reflux, intercostal myogenous chest pain) on the case report form directly after completing history taking, physical examination and possible ECG-examination and before reading and marking the test result of the PoC H-FABP-test on the same form. This procedure is seen as the next-best option after complete blinding, which is impossible to realize in practice since test results have to be read at the point of care.

In addition, after diagnosis and decision whether or not to refer are documented on the case report form by the GP, a rapid PoC H-FABP-test will be performed by the GP in finger prick blood.

Participating GPs will be informed that the PoC H-FABP-test is currently under study and that the test results can neither be included in their diagnostic conclusion nor in their decision to refer. Still, the GP is free to revise his or her decision not to refer to the cardiologist at any moment of the encounter. Such revised decision should also be recorded. For research purposes however, it is most important for us to record and analyze the initial decision of the GP, before PoC H-FABP-testing is performed.

The participating GP will send the case report form (and ECG, if present) electronically or by telefax to the research team in Maastricht or Leuven. The research team will contact the GP and, if referral has taken place, the hospital 30 days after inclusion to collect all relevant patient data (hospital discharge, GP medical record, patient test results such as biomarkers and ECG). Final diagnosis will then be set by an independent expert panel.

Study burden and risks

Burden is very low, there is no particular risk.

Contacts

Public
Selecteer

Peter Debyeplein 1
Maastricht 6229 HA
NL
Scientific
Selecteer

Peter Debyeplein 1
Maastricht 6229 HA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Thoracic complaints possibly matching acute coronary syndrome;* any ventrothoracic chest pain or oppression (including oppressive chest pain and burning sensation on the chest not typical for gastric reflux)
* anxiety with referral to the chest region
* pain in the dorso- or laterothoracic region, in the left or right upper arm, in the neck-/jaw region or in the epigastric region.

Patients presenting dyspnoe, nausea, vomiting, diaphoresis, fatigue, paleness, walking instability, faintness, near-collapse and/or collapse are only included when at least one of the above mentioned complaints of pain are present as well.

Exclusion criteria

- complaints present for more than 24 hours
- evident clinical suspection for acute cardiac cause / acute situation where all attention has to be on supporting the patient
- no written informed consent
- a traumatic cause is present
- complaints are presented that can be regarded as a recurrence of earlier complaints with clear diagnosis in the past (hyperventilation, stable AP)
- death of unidentified cause.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	14-10-2013
Enrollment:	600
Type:	Actual

Medical products/devices used

Generic name:	point of care test
Registration:	No

Ethics review

Approved WMO Date:	28-08-2013
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	14-03-2014
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	27-05-2014
Application type:	Amendment

Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	29-07-2014
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	08-09-2014
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	17-06-2015
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	02-05-2016
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	25-05-2016
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT01826994
CCMO	NL43078.068.12