HEART-GP: developing a rapid rule-out strategy for acute cardiac conditions in patients with acute-onset chest pain in out-of-hours primary care

Published: 03-02-2023
Last updated: 24-05-2024

The goals of our study are: 1) to evaluate the performance of a single hs-troponin measurement using universal and sex-specific cut-off values; 2) to evaluate whether embedding hs-troponin in a clinical risk score (HEART, INTERCHEST, Marburg Heart...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Observational invasive

Summary

ID

NL-OMON51574

Source
ToetsingOnline

Brief title
HEART-GP

Condition

- Cardiac disorders, signs and symptoms NEC

Synonym
acute chest pain, chest discomfort

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC

Source(s) of monetary or material Support: Ministerie van OC&W,Hartstichting

Intervention

Keyword: acute coronary syndrome, chest pain, primary care, rule out

Outcome measures

Primary outcome

Diagnostic test characteristics (sensitivity, specificity, accuracy, NPV and

PPV) for the occurrence of major adverse cardiovascular events (MACE) within 6

weeks of the index consultation.

Secondary outcome

-

Study description

Background summary

General practitioners (GPs) frequently assess patients with chest pain. The challenge in primary care is to make the distinction between acute cardiac conditions versus far more common, non-urgent diagnoses in an unselected case-mix of patients, with limited resources and time constraints. All while being fully aware that symptom characteristics and signs are at best a mediocre indicator in both male and female patients. Currently, both misdiagnosis and over-testing are key concerns, and standardized diagnostic strategies may help GPs to balance these risks. We propose that a recently developed fingerstick test for high-sensitivity(hs) troponin may present a breakthrough in this regard for safe rule out of acute cardiac conditions, particularly when integrated with a pretest probability assessment, using clinical risk scores.

Study objective

The goals of our study are: 1) to evaluate the performance of a single hs-troponin measurement using universal and sex-specific cut-off values; 2) to evaluate whether embedding hs-troponin in a clinical risk score (HEART, INTERCHEST, Marburg Heart Score) will further improve performance, in terms of increased efficiency without compromising safety; 3) to evaluate experiences and preferences of GPs, triage nurses and patient participants in regards to

the evaluated risk stratification tools; 4) to construct a chest pain decision rule that is safe, efficient, fit for use and implementable in out-of-hours primary care.

Central hypothesis
Evaluation of acute chest pain can be improved when GPs are provided with modern decision support tools

Study design

1) Comparative Diagnostic accuracy study
2) Qualitative study using interviews and focus group meetings

Study burden and risks

The collection of relevant patient information will take additional time during the consultation, estimated at 10-15 minutes. The measurement of hs-troponin requires a finger stick blood sample, which brings little to no additional risk to the patient. The patient will experience a short sting when a few droplets are collected. The clinical course (i.e. referral and/or treatment) will be decided by the clinical judgement of the GP.

Contacts

Public
Amsterdam UMC

Meibergdreef 9
Amsterdam 1105AZ
NL
Scientific
Amsterdam UMC

Meibergdreef 9
Amsterdam 1105AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
• Age 18 years or older
• Presence of chest pain at time of consultation, where a cardiac etiology is considered possible

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
• Hemodynamic instability
• Chest trauma preceding chest pain
• Not able to provide informed consent
• Not registered with a GP in the Netherlands

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):	17-03-2023
Enrollment:	900

Type:	Actual

Medical products/devices used

Generic name:	Atellica VTLi analyzer with hs-cTnI assay
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	03-02-2023
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
CCMO	NL82428.000.22