Primary care decision rule for chest pain using the Marburg heart score rule and troponin point of care test

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To determine the effectiveness of a decision rule compared to the usual care of GP*s for patients presenting with non-traumatic chest pain in primary care.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coronary artery disorders
Study type	Interventional

Summary

ID

NL-OMON52642

Source
ToetsingOnline

Brief title
POB HELP

Condition

- Coronary artery disorders

Synonym
Acute coronary syndrome, heart attack

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: Chest pain, Decision rule, Marburg Heart Score, POCT, Primary healthcare, Troponin

Outcome measures

Primary outcome

(1) Accuracy (specificity and sensitivity) of the decision rule for excluding

CAD and ACS and MACE (Major adverse cardiac event)

(2) Number and percentages of referrals to secondary care.

Secondary outcome

(1) Subgroup analyses will be performed for gender, socio-economic status and

duration of symptoms.

(2) Health care costs

(3) accuracy H(E)ART-score

(4) accuracy of GP*s gut feeling

(5) (non-)adherence to proposed treatment of decision rule

(6) anxiety.

Study description

Background summary

Every day, in the Netherlands, 600-1200 patients visit their general practitioner (GP) with chest pain. Chest pain may reflect coronary artery disease (CAD) or acute coronary syndrome (ACS) for which urgent referral to a cardiologist is necessary.] However, chest pain in primary care is caused by CAD in only 10-15% of patients, and by ACS in only 4-7%. Current usual practice is based on the guideline of the Dutch College of General Practitioners. This guideline states that individual signs and symptoms should direct the GP to decide on a referral to secondary care. It is known, however, that this has very low diagnostic value (sensitivity reported 69% up to 92-94%; 6-17% miss

rate).[1, 5-9] As a consequence, GPs are cautious not to miss ACS and therefore refer many patients (40-70%) to the cardiologist, at the cost of low specificity (high number of unnecessary referrals). These unnecessary referrals result in uncertainty for doctors and patients, and high health care costs for society. A decision aid to safely exclude CAD in patients presenting with chest pain in primary care could fill this gap in current practice. The Marburg Heart Score (MHS) is a clinical decision rule previously validated and currently used in primary care in Germany with a known sensitivity of 98,8% for ruling out CAD. Recently the possibility for point of care testing (POCT) of troponin became available with test results within 10 minutes, creating opportunities for use in primary care.

Study objective

To determine the effectiveness of a decision rule compared to the usual care of GP*s for patients presenting with non-traumatic chest pain in primary care.

Study design

A clustered randomized trial. 90 primary care practices include 1500 patients with chest pain.
Practices will be randomized 2:1, the intervention group will be twice the size of the control group.
Additionally, a second control group will be selected from routine care data from 2 datawarehouses.

Intervention

Clinical decision rule consisting of the Marburg Heart Score in combination with high sensitivity troponin point of care test

Study burden and risks

The burden and risk for the patient is minimal. At the time of inclusion in the interventiongroup a fingerstick bloodtest will be performed. After inclusion there will be 3 more contact moments, where patients will be asked to fill in a questionnaire. The total time needed is estimated at approximately 120 minuten.

The risk of harm to the patient following our intervention is low. However, there is always a small chance of a false negative result of the clinical decision rule. A patient may be left at home and suffer ACS there. Although the chance is small, consequences for the patient can be severe, due to delay in the diagnostic and therapeutic work-up.

It is good to realize however that in current daily practice the estimated miss-rate for ACS is estimated to be between 6-15% and developing a diagnostic

test with 100% sensitivity is impossible.

As extra safety we allow GP's to overrule the decision rule if they deem necessary for the safety of the patients. Furthermore, GP's are instructed that the diagnostic process does not end after the decision rule and another explanation/diagnosis for the chest pain needs to be sought.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Age 18 years or older
2. Presence of chest pain of new or recent onset where a cardiac etiology is considered possible.

Exclusion criteria

1. Hemodynamic instability
2. Onset of chest pain <1 hour
3. Chest trauma preceding chest pain

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-08-2021
Enrollment:	1500
Type:	Actual

Medical products/devices used

Generic name:	Troponin point of care test
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	16-04-2021
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO Date:	17-08-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	03-02-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	03-03-2023
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	05-07-2024
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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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	NL68784.058.19
Other	NL9525 en NCT05827237