Primary care decision rule for chest pain using the Marburg Heart Score and troponin point of care test

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24777

Source
Nationaal Trial Register

Brief title
POB HELP

Health condition

Acute coronary syndrome, myocardial infarction, NSTEMI

Sponsors and support

Primary sponsor: Leiden University Medical Center (LUMC)
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

1. Difference in false-positive referrals to secondary care between the intervention and control group.

2. Accuracy (specificity and sensitivity) of the decision rule for excluding CAD and ACS

Secondary outcome

1) Costs
(2) accuracy HEART-score (retrospective)
(3) quality of life
(4) (non-)adherence of GP's to the decision rule
(5) patient reassurance
(6) accuracy of GP's gut feeling
(7) cardiologist's advice after consultation

Study description

Background summary

A clustered randomized controlled trial to determine the effectiveness and safety of a decision rule compared to the usual care for patients presenting with non-traumatic chest pain in primary care in the Netherlands. The decision rule is a combination of the Marburg Heart Score and a hs-troponin I point of care test. Primary end points are the safety of the decision rule (accuracy) and the effectiveness (referrals to secondary care).

Study objective

We hypothesize that by use of the decision rule, compared to usual care, the GP's specificity will increase, following a 10% decrease in false-positive referrals. Provided that sensitivity sufficient to guarantee patient safety

Study design

Inclusion, and 1, 6 and 26 weeks after inclusion

Intervention

Clinical decision rule

Contacts

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Eligibility criteria

Inclusion criteria

>18 years
New, non traumatic chest pain where a cardiac etiology is considered possible

Exclusion criteria

Hemodynamic instability
<1 hour since onset of pain

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-06-2021
Enrollment:	1500
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	02-06-2021
Application type:	First submission

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
NTR-new	NL9525
Other	METC Leiden-Den Haag-Delft (METC-LDD) : p20.013

Study results