Fast Assessment and Management of Chest Pain without ST-elevation in the Pre-hospital Gateway;The implementation phase

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The overall aim of this study is to investigate whether the HEART score, which has proven to be safe in previous studies, can be implemented on large scale.

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

Summary

ID

NL-OMON45480

Source
ToetsingOnline

Brief title
FAMOUS TRIAGE 3

Condition

- Coronary artery disorders

Synonym
Chest pain, NSTEMI

Research involving
Human

Sponsors and support

Primary sponsor: Isala Klinieken
Source(s) of monetary or material Support: Isala academie via I&W fonds

Intervention

Keyword: Chest-pain, HEART score, NSTEMI, pre-hospital triage

Outcome measures

Primary outcome

The primary endpoint is the occurrence of MACE at 6 weeks of inclusion in the total group. MACE includes: myocardial infarction, PCI, CABG, death by all causes.

Secondary outcome

- The occurrence of MACE at 6 months of inclusion.

- Number of patients that are secondarily referred to the hospital with a HEART score of <=3 at 6 weeks and 6 months after inclusion.

- Discharge diagnosis of all patient primarily or secondarily referred to the hospital within 6 months after inclusion.

- Health care costs.

- The number of inter-hospital transfers between PCI and non-PCI centres in intermediate and high risk patient groups.

- Length of hospital stay.

- Performed diagnostics.

- Cause of death.

- Differences in patient characteristics between the low, intermediate and high risk groups.

- Quality of life obtained with SF36 questionnaire at 6 months.

Study description

Background summary

Of chest pain persons presenting to the emergency department (ED), only 20-30% have an acute coronary syndrome and at least 50% of persons have a non-cardiac cause for their complaints. This cause is often harmless and does not require hospitalization or further investigations. Therefore those persons can be discharged from the emergency department within hours. To support an efficient routine practice in chest pain patients presenting to the emergency department practice, a risk stratifying instrument named the HEART score was developed and validated by Backus et al., 2013.
In 2012, the first phase of the FAMOUS TRIAGE study was initiated to develop an appropriate pre-hospital risk stratification tool for chest pain patients. Later on, the decision was made to further investigate whether the HEART score can be used as a pre-hospital risk stratification tool instead of designing a new risk stratification tool. In this first phase, Troponin was determined in hospital from a pre-hospital collected blood sample.
In January 2016, the second Famous Triage phase was started in which the pre-hospital HEART score was completely calculated by ambulance nurses including a point of care (POC) Troponin measurement. Until now all results show that persons with a HEART score of three or lower can be monitored at home safely.
The third phase of Famous Triage has not yet been precisely described in the design paper or METC approved protocol (W13.039) about the first and second phase of Famous Triage. This protocol is written to present, and attain approval for, the third phase of Famous Triage. In this phase, pre-hospital triage takes place in a controlled, standardized way in which low risk patients will be monitored at home instead of the emergency department. This phase 3 protocol includes a new sample size calculation, explains how patients are included together with the obtaining of a short informed consent form and describes how monitoring at home is organized.

Study objective

The overall aim of this study is to investigate whether the HEART score, which has proven to be safe in previous studies, can be implemented on large scale.

Study design

This is a prospective, non-randomized, interventional multicenter study.

Intervention

Patients with a HEART score of 3 or lower will be observed at home instead of

at the emergency department when they give informed consent.

Study burden and risks

This study comprehends the shift of observation and risk stratification in low risk patients. There is no expected extra risk or burden for participants. Moreover, low risk patients might experience benefit by monitoring at home instead of at the ED.

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

Chest pain persons without ST segment elevation that are visited by an ambulance

Exclusion criteria

- Comatose state
- Cognitive impairment
- Pregnancy
- Shock
- Cardiac asthma
- Sustained ventricular tachyarrhythmia
- Electrocardiographic ST-segment elevation
- Endstage renal disease
- No pre-hospital 12-lead ECG performed or available
- An obvious non-cardiac cause for chest complaints (trauma, pneumothorax, pneumonia, etc.)
- Strong suspicion of aortic dissection or pulmonary embolism

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-09-2018
Enrollment:	545
Type:	Actual

Medical products/devices used

Generic name:	Roche h232 point of care analyzer
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	22-01-2018
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	14-05-2018
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	04-12-2018
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)

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	NL60396.075.16