No registrations found.

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

Summary

Source

NTR

Brief title

FAMOUS TRIAGE 3

Health condition

non-STEMI
myocardial infarction
hartinfarct
myocardial infarction
HEART-score
paramedics
ambulance nurses
pre-hospital

Sponsors and support

Primary sponsor :	Sponsor: Isala, Zwolle. Principal investigator: J.P. Ottervanger
Source(s) of monetary or material Support :	Isala I&W research fund Roche Diagnostics for materials

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Secondary outcomes are the occurrence of MACE within 6 months of inclusion, the number of patients that are secondarily referred to the hospital for cardiac reasons with a HEART score of ≤3 within 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, length of hospital stay, performed diagnostics, cause of death, differences in patient characteristics between the low, intermediate and high risk groups, quality of life.

Study description

Background summary

Chest pain suspected for non-ST segment elevation (non-STEMI) is a diagnostic challenge for health care providers since there is a wide variety in causes. Earlier management is possible when differentiation between low- and high risk patients is performed prehospital by paramedics. The HEART score proved to be a feasible and adequate tool to achieve this. So far all pre-hospital HEART studies have been observational. We set out to quantify the impact of the implementation of the pre-hospital HEART score in daily practice.

Study objective

Risk stratifying by ambulance nurses using the HEART score in patients with suspected non-STEMI is feasible and safe.

Study design

- Inclusion time

- primary endpoint 45 days follow up

- secondary endpoints 6 months follow up

Intervention

pre-hospital HEART assessment including POC troponin. Patients with low risk (HEART-score 3 or lower) will be asked for informed consent to be observed at home. A second HEART score will be performed by paramedics after 3-12 hours.

Patients at intermediate or high risk (HEART-score 4 or higher) will be transfered to a hospital and asked for informed consent for dossier study and contact for study questions when needed.

Contacts

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Eligibility criteria

Inclusion criteria

All out-of-hospital patients visited by an ambulance with a pre-hospital suspicion of non-STEMI ACS at first medical contact

Age ≥ 18 years

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

Recruitment

NL

Recruitment status :	Pending
Start date (anticipated) :	01-04-2018
Enrollment :	1090
Type :	Anticipated

Ethics review

Positive opinion

Date :	26-02-2018
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	NL6833
NTR-old	NTR7070
Other	METC Zwolle : 170526

Study results