Acute rule out of non-ST segment elevation acute coronary syndrome in the (pre)hospital setting by HEART score assessment and a single point of care tropnin: the ARTICA randomized trial

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To assess whether a prehospital rule-out strategy using the modified HEART score and an ambulant single troponin assessment with point-of-care (POC) troponin T device employed by paramedics can cost-efficiently and safely rule out ACS as compared to...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON49843

Source
ToetsingOnline

Brief title
ARTICA randomized trial

Condition

- Other condition
- Cardiac disorders, signs and symptoms NEC

Synonym
chest pain and non ST-segment elevation acute coronary syndrome

Health condition

hartaandoeningen, non ST elevatie acuut coronair syndroom en pijn op de borst

Research involving
Human

Sponsors and support

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

Intervention

Keyword: chest pain, non ST-segment acute coronary syndrome, point of care troponin, prehospital triage

Outcome measures

Primary outcome

The primary aim of the study is the assessment of health care costs. Cost and quality adjusted life years (QALYs) will be measured on a per patient basis over the relevant time path in which the (most important) differences in both measures between both arms manifest themselves. Cost-effectiveness will be expressed in terms of cost per QALY gained.

Secondary outcome

The secondary aim is to determine safety, as shown by previous studies i.e. major adverse cardiac events (MACE) less than 1.5% at one, six and 12 months. At last we will evaluate the potential improvement in patient care, both for patient convenience (by using questionnaires after 30 days of follow-up concerning the patient*s experience: direct reassurance for very low risk of NSTE ACS as for health care costs (no ambulance transfer and admittance to the ER).

Study description

Background summary

Of all patients suspected of non ST-segment elevation acute coronary syndrome (NSTE-ACS), the majority is currently presented at hospital emergency departments (ER) to rule out ACS. In patients with a low risk profile, NSTE-ACS is however rarely found. All these presentations on the other hand contribute to the overcrowding of the ER and health care costs. Recent studies have suggested that using a simple prehospital rule-out strategy including the modified HEART score with ambulant troponin T assessment, can help ambulance personnel to discriminate between high and low risk of NSTE-ACS. In the latter, it was shown that unnecessary ER presentations may potentially be prevented and costs reduced
HEALTH CARE EFFICIENCY PROBLEM: Emergency departments are increasingly overcrowded and ambulance services are confronted with more patient transfers. In 2012 the National Institute for Public Health and the Environment (RIVM) revealed that 140.369 patients were evaluated with chest pain, but eventually no ACS or angina pectoris was found. Almost 75.000 patients (53%) undergo observation at the ER, but are discharged without a final diagnosis of NSTE-ACS [7]. The Dutch Health Authority (NZA) has become aware of this *chest pain* burden and made a recent general recommendation

Study objective

To assess whether a prehospital rule-out strategy using the modified HEART score and an ambulant single troponin assessment with point-of-care (POC) troponin T device employed by paramedics can cost-efficiently and safely rule out ACS as compared to standard ER evaluation.

HYPOTHESIS: pre-hospital triage in patients with low risk of NSTE-ACS will reveal a large saving in health care resources in favor of the pre-hospital rule strategy with additional GP management. At 12 months the strategy will corroborate with a very low event rate (MACE rate < 1.5%

Study design

Prospective, randomized controlled, investigator-initiated, multicentre study

Intervention

Patients will be randomised 1:1, to (A) a management by their general practitioner or (B) regular hospital evaluation, in which patients will undergo rule out of ACS at the chest pain unit according to local protocol.

Study burden and risks

Previous investigation have shown that one third of the patients presenting with ACS-symptoms are at low risk for ACS. This group will be randomly assigned to standard hospital evaluation or prehospital management (general practitioner, conservative). Randomised patients are all at low risk for ACS and might benefit from conservative prehospital treatment, because this strategy is safe and transfer with hospitalisation can lead to unnecessary utility of medical resources and increase costs.

Contacts

Public
Radboud Universitair Medisch Centrum

Geert Grooteplein 10
Nijmegen 6525 GA
NL
Scientific
Radboud Universitair Medisch Centrum

Geert Grooteplein 10
Nijmegen 6525 GA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients with symptoms suggestive for non ST-segment elevation acute coronary syndrome with symptom duration of at least two hours, a HEART score equal or less than 3 and a point of care troponin below the lower limit of the measuring range

Exclusion criteria

- Patients with an acute ST elevation myocardial infarction
- Patients presenting an obvious non-cardiac cause for the chest complaints who need evaluation at an emergency department, e.g. trauma, pneumothorax, sepsis, etc.
- Patients in comatose state, defined as an EMV <8
- Patients with known cognitive impairment
- Pregnancy or intention to become pregnant during the course of the study
- Patients presenting cardiogenic shock, defined as: systolic blood pressure <90mmHg and heart rate >100 and peripheral oxygen saturation <90% (without oxygen administration)
- Patients presenting with syncope
- Patients presenting with signs of heart failure
- Patients presenting with heart rhythm disorders and second or third degree atrioventricular block
- Patients with known end-stage renal disease (dialysis and/or MDRD < 30 ml/min)
- Patients without a pre-hospital 12-lead ECG performed or available
- Patients suspicious of aortic dissection or pulmonary embolism
- Patients with confirmed AMI, PCI or CABG <30 days prior to inclusion
- Communication issues with patient/language barrier
- Decision of a present general practitioner to evaluate the patient at ER
- Decision of the consultant cardiologist to evaluate patient at the ER irrespective of HEART score
- Any significant medical or mental condition, which in the Investigator*s opinion may interfere with the patient*s optimal participation in the study

Study design

Design

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

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-03-2019
Enrollment:	866
Type:	Actual

Ethics review

Approved WMO Date:	27-11-2018
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	19-12-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	02-12-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	21-10-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL66755.091.18