Cost-effectiveness study of the HEART score in the management of patients with chest pain presenting in the emergency room

Published: 05-02-2013
Last updated: 01-05-2024

To quantify the impact of the use of the HEART risk score on patient outcome (major adverse cardiac events(MACE) and quality of life) and on costs in patients with chest pain presenting at the emergency room.

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

Summary

ID

NL-OMON39519

Source
ToetsingOnline

Brief title
Cost-effectiveness of the HEART score in chest pain patients

Condition

- Coronary artery disorders

Synonym
coronary artery disease, occlusion of the arteries of the heart

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: chest pain, cost-effectiveness, HEART score, implementation

Outcome measures

Primary outcome

All patients will be followed for three months to assess the study outcome parameters.

Primary outcome: occurrence of MACE (i.e. acute myocardial infarction (AMI), Percutaneous Coronary Intervention (PCI), Coronary Artery Bypass Grafting (CABG) or death) within 6 weeks after presentation (non-inferiority approach).

Secondary outcome

3 months incidence of MACE, quality of life and cost-effectiveness of the intervention compared with usual care. Furthermore, the number of missed events will be recorded. Also, we will be able to assess future biomarkers (like DNA-markers) in the extra bloodsample.

furthermore, we will be able to assess possible women-specific risk factors by means of the women-specific questionnaire.

Study description

Background summary

Chest pain is one of the most common reasons for patients to present to the emergency department (ED). Decision making in these patients suspected of acute coronary syndrome (ACS) is hampered by limited predictive power of individual patient characteristics (reference 16-18 in protocol). Recently, the HEART score was developed and extensively validated in various (external) patient populations and its predictive effectiveness has been proven. Estimations of

total costs of cardiology care in low HEART score patients have been made in a pilot study, revealing potential annual savings of >35 million euro per year for the Netherlands.

Study objective

To quantify the impact of the use of the HEART risk score on patient outcome (major adverse cardiac events
(MACE) and quality of life) and on costs in patients with chest pain presenting at the emergency room.

Study design

Prospective stepped wedge trial including 6600 patients in 10 Dutch hospitals. During 11 months, patients presenting with chest pain to the ER of participating hospitals will be included in the study. First, all hospitals will apply *usual care* to all patients, i.e. assessment without application of the HEART score. Then, during a 10 month period, each month 1 randomly allocated hospital will sequentially start to apply the HEART score (previously developed and validated by our group) in all chest pain patients (intervention period); during this intervention period patients with a HEART score 0-3 will not be admitted to the hospital (in accordance with the results of our validation studies), and patients with a HEART score above 3 will be treated according to current guidelines.

Intervention

The HEART score is a validated risk score for all patients presenting with chest pain at the ED. The HEART score consists of the following clinical elements: History, ECG, Age, Risk factors and Troponin. Each of the five factors can be appreciated with 0, 1 or 2 points. The sum of all five elements results in a score of 0-10, thus dividing patients in a low-, intermediate- or high-risk group. The patients in the low-risk group are discharged, with a troponin assessment at home within 72 hours. The patients in the intermediate group are admitted to the hospital for observation and further investigation. The high-risk group receives immediate intervention or treatment. At all times, the attending doctor can decide to choose otherwise when he feels the risk stratification is somehow not consistent will his own experienced view.

Study burden and risks

To prevent that during the intervention period, a subclinical / asymptomatic ischemic cardiac event will not be detected in low-risk patients sent home, all patients in the low risk group (who had there first troponin measurement at the ED < 8 hours) will be visited at home by trained personnel from the local ambulant laboratory to assess troponin levels within 72 hours after discharge.

The participating patients will be asked to fill in a quality of life questionnaire at day one, and at two weeks and three months after presentation at the ED. When indeed the HEART score would shown to be cost-effective and safe, patient burden will decrease considerably, with less provocative testing and/or coronary imaging before discharge. Also an extra blood sample will be collected during primary ED presentation, during the first blood collection for troponin measurement. Women will be asked to fill in an 2-page women-specific questionnaire at the ED.

Contacts

Public
Universitair Medisch Centrum Utrecht

Universiteitsweg 100 100
Utrecht 3584 CG
NL
Scientific
Universitair Medisch Centrum Utrecht

Universiteitsweg 100 100
Utrecht 3584 CG
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

patient presenting with chest pain at the emergency room

Exclusion criteria

Children (age <18 years)
Subjects who are (for whatever reason) not able to fill in questionnaires
STEMI (ST-elevation myocardial infarction)

Study design

Design

Study type:	Interventional
Intervention model:	Other
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):	01-07-2013
Enrollment:	6600
Type:	Actual

Ethics review

Approved WMO Date:	05-02-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	12-09-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO	

Date:	29-10-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	25-06-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	26-11-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL40176.041.12