Direct uitsluiten van het hartinfarct in de ambulance door afname van een vragenlijst en bepalen van een hartspecifieke eiwit

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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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23618

Bron
NTR

Verkorte titel
ARTICA

Aandoening

chest pain, myocardial infarction, non-ST segment elevation acute coronary syndrome, troponin

Ondersteuning

Primaire sponsor: Radboud university medical center, Department of Cardiology
Overige ondersteuning: ZonMW - projectnumber 852001942

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary endpoint consists of a significant reduction in health care costs at 30 days by a decrease in health care resources and use of ambulance

Toelichting onderzoek

Achtergrond van het onderzoek

Of all patients suspected of non ST-segment elevation acute coronaire syndrome (NSTE-ACS), the majority is currently presented at the hospital emergency departments (ER) to rule out NSTE-ACS. In patients with a low risk profile for ACS, NSTE-ACS is however rarely found. All these presentations on the other hand contribute to an overcrowded ER, increase of patient transfers by ambulance services and a problematic increase in health care costs.

Recent studies have suggested that by using a simple rule-out strategy including a risk algorithm and a point-of-care (POC) troponin device, ambulance personnel can discriminate between high and low risk of NSTE-ACS. In the latter, adequate pre-hospital risk stratification may prevent unnecessary ER presentations and consequently reduce costs. The HEART (History, ECG, Age, Risk factors and Troponin) risk score is a simple validated risk tool which can facilitate risk stratification and decision making on the spot. Low risk chest pain patients can easily be identified and early discharged from the ER with very low risk of major adverse cardiac events (MACE). With regard to its friendly near the patient use and fast turn-around-time, POC troponin devices have increasingly gained popularity and its application is ideal for use in the pre-hospital setting.

Research quastion: to assess the cost-effectiveness and efficacy of ambulance triage with further general practitioner management versus standard hospital admission in patients with symptoms suggestive for NSTE-ACS, but with very low risk (HEART score equal or less than 3, POC troponin below the upper referernce limit.

Doel van het onderzoek

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%)

Onderzoeksopzet

1 month: health care costs: cost per gained quality adjusted life years (QUALY), iMTA PCQ, friction cost-method, quality of health (EuroQol-5D-5L)

1 month: death, acute coronary syndrome, stroke

6 months: death, acute coronary syndrome, stroke

12 months: death, acute coronary syndrome, stroke. Health care costs

Onderzoeksproduct en/of interventie

Pre-hospital triage with management by the General practitioner versus pre-hospital triage with standard referral to the hospital

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Age at least 18 years; male ánd female

- All out-of-hospital patients with chest pain or symptoms suggestive of ACS initially visited by an ambulance with an indication for transfer to a hospital to evaluate and rule out ACS

- Symptom duration for at least two hours

- Modified HEAR(T) score less or equal than 3

- A point of care troponin below the upper reference limit (for patients stratified to prehospital management by the general practitioner)

- The patient has been informed of the nature of the study, agrees to its provisions and has provided written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Electrocardiographic ST-segment elevation

- 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	03-01-2019
Aantal proefpersonen:	866
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Toelichting
Individual participant data that underlie the results (text, tables, figures and appendices) reported in the article will be shared after deidentification. Additionally, the study protocol will be available. The data and study protocol will be available beginning 6 months and ending 5 years following article publication. To gain access, researchers have to provide a methodologically sound proposal. The future research should also concern the subject “chest pain”. The proposals should be directed to the corresponding author in order to gain access.

The data requestors will have to sign a data access agreement before gaining access. The data will be shared using DANS EASY

Ethische beoordeling

Positief advies

Datum:	10-07-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7148
NTR-old	NTR7346
Ander register	METC Arnhem-Nijmegen : 2018-4676

Resultaten

Samenvatting resultaten
BMJ Open 2020;10:e034403. doi: 10.1136/bmjopen-2019-034403