A prospective cohort study to improve the AccUracy of Referrals to the emerGency departmEnt of patieNts with chesT pain: to decrease the delay in acute coronary syndrome patients and rule out non-cardiac chest pain patients (URGENT)

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Observational invasive

Summary

ID

NL-OMON45470

Source
ToetsingOnline

Brief title
Improving the accuracy of referrals of patients with chest pain

Condition

- Cardiac disorders, signs and symptoms NEC

Synonym
acute coronary syndrome, hartattack

Research involving
Human

Sponsors and support

Primary sponsor: Viecuri Medisch Centrum voor Noord-Limburg
Source(s) of monetary or material Support: Afdeling Cardiologie te VieCuri Venlo,Philips

Intervention

Keyword: Acute coronary syndrome, General practitioners cooperation, Heart score, Non cardiac chest pain

Outcome measures

Primary outcome

The main study point is a more accurate referral of patients with suspected ACS

to the cardiac ED and thus the concordance of suspected ACS and the actual

diagnosis. The prompt referral of ACS patients will also be assessed through

evaluation of the delays in these patients. Both of these endpoints will be

compared to the baseline registry that has been executed from 1st of September

2015 until 1st of March 2016.

Secondary outcome

The secondary study endpoint is MACE at 1 year follow-up. This is a combined

endpoint of:

1. Mortality

2. Any ischemic cardiac event

a. ST-elevated myocardial infarction

b. Non ST-elevated myocardial infarction

c. (Unstable) angina pectoris

d. Percutaneous coronary intervention

e. Coronary artery bypass graft surgery (CABG)

f. Resuscitation

Study description

Background summary

This study aims to aid the general practitioner (GP) in the diagnostic dilemma of chest pain patients. Patients with acute coronary syndrome (ACS) should be referred to the hospital promptly, though referring all patients with chest pain is not feasible, as up to 80% of the patients with chest pain in the primary care do not have ACS.

Study objective

The primary objective is to refer patients who contact the out-of-hours GP cooperation (GPC) with suspicion of ACS more accurately.

The secondary objectives are:
1. A registry of all patients referred to the emergency department (ED) with suspected ACS to assess the appropriateness of referrals, either by EMT, GP or as self-referrals. This will be compared to the baseline registry performed from the 1st of September 2015 until the 1st of March 2016. We will include all patients referred to the hospital, to not miss any patients who have contacted the GPC and have been referred promptly to the ED.
2. A comparison of patient characteristics, signs and symptoms to the baseline registry to evaluate the clinical differences between ACS and NCCP patients.
3. A comparison of patients referred promptly after nurse phone triage at the GPC at baseline (before intervention) and after intervention.
4. A comparison of patients referred to the ED after evaluation by the GP with the Heart score including ECG and troponin, compared to referral at baseline without these tests.
5. Analytical comparison of point of care tester troponin tester versus high sensitive troponin-I (hsT-I) at second evaluation with blood test.
6. The mortality and major adverse cardiovascular events (MACE) at 30 days, 6 months and 1 year.

Study design

This study is a prospective, observational, prevalence-based cohort study within the standard care of ACS patients.

Study burden and risks

Patients enrolled within this study will receive a fingerstick blood test and ECG recording at the GPC and for follow-up purposes a fingerstick blood test and a venous blood test at least four hours after first blood test (and up to 24 hours after). We may follow-up within a year if we can not obtain the required information from medical records. We expect no adverse events and there are no expected risks associated with this protocol. We expect patients with ACS to be referred more accurately and more promptly to the ED and thus lowering risks.

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

All patients with chest pain or other complaints suspect of acute coronary syndrome can be included in which the GP at the GP cooperation is in need of further diagnostics to come to a decision.

Exclusion criteria

Patients younger than 18 years.
Patients in which a typical history and/or physical examination requires immediate referral; high suspicion of acute coronary syndrome.
Patients in which an acute non-coronary diagnosis is suspected, e.g. pulmonary embolism, thoracic aortic dissection etc.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-04-2017
Enrollment:	500
Type:	Actual

Ethics review

Approved WMO

Date:	28-02-2017
Application type:	First submission

Review commission: METC Z: Zuyderland-Zuyd (Heerlen)

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	NL60045.096.16

Study results

Date completed: 01-11-2018

Actual enrolment: 40

Summary results
Trial is onging in other countries