The role of telecardiology and h-FABP/troponine in family practice in early detection of myocardial infarction, in patients with atypical complaints: a new diagnostic approach for the general practitioner

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Ethical review	Not approved
Status	Will not start
Health condition type	Myocardial disorders
Study type	Interventional

Summary

ID

NL-OMON32288

Source
ToetsingOnline

Brief title
The CAVARI study (Cardio Vascular Risk)

Condition

- Myocardial disorders

Synonym
Acute coronary syndrome/ myocardial infarction

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Friesland Zorgverzekeraar,Friesland zorgverzekeraar/ IPT (Instituut voor Preventie en Telemedicine),IPT (Instituut voor Preventie en Telemedicine)

Intervention

Keyword: family practice, H-FABP, telecardiology, troponine

Outcome measures

Primary outcome

Difference in percentage necessary hospitalisation/ referal to a cardiologist

Secondary outcome

not applicable

Study description

Background summary

Most patients who present with myocardial infarction have an atypical presentation, which makes it for the general practisioner a diagnostical problem. Several studies have indicated that 20-40% of the events remain clinically unrecognized. On the other hand, a lot of patients unnecessary will be refered to a cardiologist. There is a need for new diagnostic tools to improve the early detection of a myocardial infarction. Telecardiology and the CardioDetect are reliable and valid tools, with a high diagnostic accuracy for the early detection of acute myocardial infarction. Prehospital use will raise necessary hospitalisation and will detect more myocardial infarction.

The diagnostic accuracy of the CardioDetect that we found in our pilotstudy is not equal to the literature. In this next study it's important to look at the diagnostic accuracy, the reliability and the validity of this test.

Study objective

In this study we investigate the prehospital use of a Tele-ECG and the

CardioDetect. We will use the results to see if help of these diagnostic tools will raise the percentage necessary hospitalisations.
We will also investigate the diagnostic accuracy, the reliability and the validity of the CardioDetect.

Study design

Prospective controlled randomised interventionstudie. Patients that come to the GP, with atypical complaints will be included. Both the interventiongroup and controlgroup will be seen by a GP, which will decide his/ her policy by asking questions and physical examination (care as usual). Patients seen by the GP on a certain day will form the interventiongroup and get the possibility of a Tele- ECG and the CardioDetect. The GP also takes blood for early detection of troponin. Afterwards, the GP can change his/ her policy with help from the tests and a cardiologist (in case at least one testresult is positive). This will be noted in the electronic file. Patients seen by the GP on another day will form the controlegroup, which don't have the possibility of a Tele- ECG and the CardioDetect. They get care as usual.

Intervention

Diagnostic tools:

-Tele- ECG
-CardioDetect- which will test only h-FABP

Study burden and risks

Almost no burden en risks for the patient. An short interview will normaly be done and a ECG will take a few minutes. The fingerpunction and the venapunction give hardly no complications.

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

Atypical complaints:
atypical chest pain, atypical radiation of pain, dyspnea, vertigo, weakness, sweating, vomitting, palor.;De GP has doubts about the diagnoses and doesn't exactly know if there is a cardial cause. There is no suspicion of an acute coronary syndrome and an emergency referal is not needed.

Exclusion criteria

insanity
age < 30 years
recent muscle injury/ recent chest trauma
cardiogenic shock
De GP has a suspicion of an acute coronary syndrome
renal insufficienty

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:	Will not start
Enrollment:	170
Type:	Anticipated

Ethics review

Not approved

Date:	22-12-2008
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

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	NL21559.099.08