Risk factors associated with acute coronary syndrome in patients with acute chest pain symptoms

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To determine if the ESC ACS guidelines (the currently used 0h/3h rapid rule out protocol, as well as the future 0h/1h rapid rule out protocol) can be applied for ruling out ACS on the ED/CCU for patients with cocaine associated chest pain.

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

Summary

ID

NL-OMON47778

Source
ToetsingOnline

Brief title
RISK trial

Condition

- Cardiac disorders, signs and symptoms NEC

Synonym
acute myocardial infarction, Heart attack

Research involving
Human

Sponsors and support

Primary sponsor: OLVG
Source(s) of monetary or material Support: Roche diagnostics,Stichting Teaching Hospital OLVG en Roche diagnostics

Intervention

Keyword: ACS, cocaine, observation

Outcome measures

Primary outcome

Primary parameter is the development of ACS. The end point is >4 weeks after presentation.

Secondary outcome

Secondary endpoints are: observation time on the department; re-admittance to hospital after discharge; recurrent chest pain with presentation to medical specialist; recurrent chest pain without presentation to medical specialist; no recurrent chest pain symptoms, discontinuation or continued cocaine abuse.

Study description

Background summary

No protocol for the treatment of cocaine associated chest pain (CACP) is subscribed by the Dutch Cardiology association or the Dutch association for Emergency Medicine. The American Heart Association refers to a review article in their advice for a twelve hour observation period in patients with CACP to exclude the development of an AMI. This advice is based on limited and outdated literature, without the use of modern high sensitive troponins. A questionnaire amongst Dutch emergency physicians and cardiologist reveals that there is a variety in treatment and observation times for CACP patients, but the majority treats ands observes patients according to the ESC ACS guidelines. Therefor we can speak of this guideline as the standard of care for treatment of CACP, in contrary to the 12 hour observation period as advices in the outdated protocol of the AHA. This conclusion provided the hypothesis for this study: the ESC ACS guideline is valid for exclusion of ACS in patients with CACP.
This guideline advises discharge of CACP patients with a low- to intermediate cardiac risk profile if there are no abnormalities on the EKG suspect for STelevated myocardial infarct (STEMI) and if there is no relevant rise in cardiac enzymes. According to the ESC ACS guidline there are 2 algorithms to decide relevant rise in troponins: 1) an algorithm in which a relevant rise can

be detected after 3 hours with use of high sensitivity troponins (0h/3h rapid rule out protocol); 2)) an algorithm in which a relevant rise can be detected after 1 hours with use of high sensitivity troponins (0h/1h rapid rule out protocol). Both algorithms are valid. The first algorithm is the general standard of care, the second algorithm is new, and therefor not widely implemented yet. This implementation is expected to be very soon though, depending on financial agreements with health care insurances.

Study objective

To determine if the ESC ACS guidelines (the currently used 0h/3h rapid rule out protocol, as well as the future 0h/1h rapid rule out protocol) can be applied for ruling out ACS on the ED/CCU for patients with cocaine associated chest pain.

Study design

The study design will be a multi center, prospective, observational cohort study.

Study burden and risks

Subjects will be asked for their participation and will have to sign an informed consent form. The subjects will be treated according to the current standard of care with addition of the soon to be applied new standard of care (the currently used 0h/3h rapid rule out protocol, as well as the future 0h/1h rapid rule out protocol). This includes blood sample collection according to both protocols, ECG administration, full medical history and history of symptoms with analysis of cardiac risk factors and associated drug of abuse. Urine will be collected for drug analysis. This is all according to current standard practice, except for one extra blood sample to validate the future standard of care.
After discharge subjects will be contacted once by telephone or by email for follow up. If the subject can not be contacted and informed consent for contacting the GP has been given, the GP will be contacted once for follow up. Questions will be asked according to the primary and secundary study parameters (re-admittance to hospital after discharge; recurrent chest pain with presentation to medical specialist; recurrent chest pain without presentation to medical specialist; no recurrent chest pain symptoms, discontinuation or continued cocaine abuse). No information other than standard information after visiting the hospital will be sent to the GP.

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

-Acute chest pain symtoms
-low- to intermediate cardiac risk profile
-anamnestically positive for cocaine use past 4 days
-age > 18 years - < 46 years and toxicology screening positive for cocaine

Exclusion criteria

-high cardiac risk profile
-non english speaking
-other clearly diagnosed non cardiac causes of chest pain.

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):	12-03-2017
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO Date:	03-03-2017
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	14-11-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 22767
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
Other	NTR5500
CCMO	NL57552.100.16
OMON	NL-OMON22767