Evaluation of Secondary Prevention of Cardiac Disease by Nurse Specialists

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23674

Source
NTR

Brief title
RESPONSE

Health condition

Acute Coronary Syndrome, Preventive cardiology, Secondary Prevention of Cardiovasculair disease, Nurse Specialists

Acuut coronair syndroom, Preventieve Cardiologie, Secundaire Preventie van hart- en vaatziekten, Gespecialiceerde verpleegkundigen

Sponsors and support

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Intervention

Outcome measures

Primary outcome

Copenhagen Risk score at 12 months follow-up.

Secondary outcome

1. Smoking status

2. Exercise status

3. Body Mass Index

4. Waist-to-hip ratio

5. Blood pressure

-Systolic blood pressure

-Diastolic blood pressure

6. Glucose parameters

-HbA1c

-Fasting glucose

7. Lipid profile

-Total cholesterol

-HDL

-LDL

-Triglycerids

8. Change in Diabetes status

Risk scores:

- Copenhagen Risk score
(at 6 months)

- Europa-score26

- PROCAM-score27

- Euroscore28

- SF-36

- MacNew

Study description

Background summary

Rationale: Treatments for secondary prevention of clinical events in patients with coronary artery disease are currently sub-optimally implemented. We hypothesize that a 6 month outpatient counselling and treatment course led by a nurse, in addition to usual care, reduces the risk of recurrent clinical events compared to usual care alone.

Objective:

Primary objective: To quantify the impact of outpatient nurse-led prevention clinics on the risk of future clinical events as calculated by the Copenhagen Risk score in patients with symptomatic coronary artery disease.

Study population: Patients aged 18-80 years who have been hospitalised less than 8 weeks before inclusion for an acute coronary syndrome.

Intervention: Intervention group is seen up to 4 times in 6 months following occurrence of acute coronary syndrome at a nurse-led outpatient clinic in addition to usual. Control group receives usual care only.

Main study parameters: The following parameters (and change herein) are compared at baseline, at 6 months and at 12 months after inclusion in study in both study groups:

1. Copenhagen Risk score

2. Smoking status

3. Exercise status

4. Body Mass Index

5. Waist circumference

6. Systolic blood pressure

7. Diastolic blood pressure

8. Diabetes status, fasting glucose, HbA1c levels

9. Total cholesterol, HDL, LDL, Triglycerides

Study objective

A 6 month outpatient counselling and treatment course by a nurse (in addition to usual care) reduces the risk of recurrent clinical events compared to usual care alone

Study design

Baseline

follow-up 6 months

follow-up 12 months

Intervention

Intervention group is seen up to 4 times in 6 months following occurrence of acute coronary syndrome at a nurse-led outpatient clinic in addition to usual care. The nurse-led outpatient clinic focuses on lifestyle, established cardiovascular risk factors and medication adherence.

Contacts

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Eligibility criteria

Inclusion criteria

Patients between 18-80 years hospitalised less than 8 weeks before inclusion for an acute coronary syndrome, either unstable angina or acute myocardial infarction, will be included

Exclusion criteria

Patients will be excluded if clinic visits are not feasible, if not available for follow-up, if surgery, percutaneous coronary intervention or other interventions are expected within 8 weeks, if life expectancy is considered limited, if previously enrolled in NLPC or if NYHA class 3 or 4 from heart failure.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-10-2006
Enrollment:	1000
Type:	Actual

Ethics review

Positive opinion

Date:	24-04-2008
Application type:	First submission

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
NTR-new	NL1244
NTR-old	NTR1290
Other	MEC : 06/109
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results

N/A