Randomised Evaluation of Secondary Prevention by Outpatient Nurse SpEcialists

Published: 01-06-2006
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To quantify the impact of outpatient nurse-led prevention clinics on the risk of future clinical events in patients with symptomatic coronary artery disease.

Ethical review	Approved WMO
Status	Pending
Health condition type	Coronary artery disorders
Study type	Interventional

Summary

ID

NL-OMON30357

Source
ToetsingOnline

Brief title
RESPONSE

Condition

- Coronary artery disorders
- Glucose metabolism disorders (incl diabetes mellitus)
- Lifestyle issues

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Astra Zeneca,AstraZeneca Nederland

Intervention

Keyword: cardiovascular diseases, coronary disease, nurse practitioners, secondary prevention

Outcome measures

Primary outcome

Change in status of Copenhagen Risk score and modifiable risk factors for

coronary heart disease: smoking, exercise, excess weight, dyslipidaemia,

hypertension, diabetes mellitus compared with group receiving usual care.

Secondary outcome

- Quality of life

- Evaluation of efficiency of reaching treatment targets

- Compliance with medical treatment

- Risk scores: Europa-score, PROCAM-score, Euroscore

Study description

Background summary

Treatments in secondary prevention of clinical events in patients with coronary artery disease are are based on robust evidence but are sub-optimally implemented in the current 2nd line setting. The modifiable risk factors that are form the base prevention of cornary artery disease are smoking, lack of exercise, excess weight, dyslipidaemia, hypertension and diabetes mellitus.

Nurses are potentially better suited for this type of care, and outpatient nurse-led prevention clinics (NLPC) are being initiated in many centres across the country and abroad. However, the impact of this new approach remains largely unknown.

Study objective

To quantify the impact of outpatient nurse-led prevention clinics on the risk

of future clinical events in patients with symptomatic coronary artery disease.

Study design

A randomized clinical trial where patients are randomised into one of two groups; one intervention group that will be seen by the NLPC, one control group which will receive usual care in accordance with national guidelines

Intervention

Patients randomised to the intervention group will, in addition to usual care, be seen at the NLPC. Here they receive counselling and support to promote a healthy lifestyle, including cessation of smoking, regular exercise, healthy food choices and weight control. They will receive educational materials to be studied at home. In subsequent visits, these materials will be discussed. In addition, patients in the intervention group will be actively screened for diabetes and hypertension

Intervention group is seen 5 times in 6 months following occurrence of acute coronary syndrome at a nurse-led outpatient clinic in addition to usual care (according to national guidelines).

Study burden and risks

No experimental treatments are performed during study.

Main burdens are time investment (controls 3x 30 minutes, interventions 7x 30 minutes) and discomfort inherit in the taking of blood samples (controls 3x 16.2 mL, interventions 7x 16.2 mL). Blood pressure, weight, lenght and waist-to-hip ratio will be measured during each visit.

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

• Age 18-80 years
• Hospitalisation for an acute coronary syndrome (instabiele angina/acuut hartinfarct) less than 8 weeks before inclusion.

Exclusion criteria

• Clinic visits not feasible
• Not available for follow-up
• Surgery/percutaneous coronary intervention expected within 8 weeks
• Limited life expectancy
• Previously enrolment in nurse-led prevention clinic
• NYHA class 3 or 4 caused by heart failure

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	06-01-2006
Enrollment:	1000
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL11272.018.06