

Evaluation of Secondary Prevention of Cardiac Disease by Nurse Specialists

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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

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23674

Bron

NTR

Verkorte titel

RESPONSE

Aandoening

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

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

Ondersteuning

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Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Copenhagen Risk score at 12 months follow-up.

Toelichting onderzoek

Achtergrond van het onderzoek

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

Doel van het onderzoek

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

Onderzoeksopzet

Baseline

follow-up 6 months

follow-up 12 months

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	17-10-2006
Aantal proefpersonen:	1000
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies	
Datum:	24-04-2008
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1244
NTR-old	NTR1290
Ander register	MEC : 06/109
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten

N/A