Individual reevaluation therapy Primairy Cardiovascular Prevention

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Ethical review	Approved WMO
Status	Pending
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Interventional

Summary

ID

NL-OMON32052

Source
ToetsingOnline

Brief title
reevaluation therapy Primairy Cardiovascular Prevention

Condition

- Cardiac disorders, signs and symptoms NEC

Synonym
therapy to prevent cardiovascular disease

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: zorgverzekeraar

Intervention

Keyword: cardiovascular, prevention

Outcome measures

Primary outcome

Endpoints

• Number and proportion of patients using medication for primary prevention of cardiovascular disease who are willing to participate in a reevaluation of the cardiovascular risk.

• Number and proportion of patients who do not need preventive cardiovascular medication according to the new guidelines for cardiovascular risk management and who are willing to discontinue the medication.

Secondary outcome

The savings in yearly costs of medication duet o discontinuation of medication (total costs in euros for this medication of all patients in 2007 vs 2010, extrapolated on the basis of 3% index).

Study description

Background summary

According to the new guideline for cardiovascular risk management of the Dutch College of General Practice, risk factors (NHG-standaard M84 Cardiovasculair risicomanagement), such as hypertension and hypercholesterolemia, are treated in association with each other, through the calculation of one risk score. The guideline defines two categories: patients with previous cardiovascular disease or diabetes and patients without this.

Within the Zorgcoöperatie Katwijk langs de Rijn U.A., general practitioners and

practice assistants use a protocol for patients with diabetes. In the near future, in collaboration with the hospitals in the area a protocol will be developed for the prevention of cardiovascular disease for patients with previous cardiovascular disease (secondary prevention). Additionally, the Zorgcoöperatie wrote a protocol in May 2007 for the primary prevention of cardiovascular disease (for patients without previous cardiovascular disease or diabetes mellitus) using the guideline for cardiovascular risk management.

One problem encountered during the development of the protocol for primary prevention are the patients using medication for hypertension or hypercholesterolemia since a long time, who would not need this medication according to the new guidelines. With these patients the general practitioner can discuss the necessity of discontinuation of the medication. Not every patient will agree to discontinuation. To find an efficient way to deal with this problem, knowledge about which patients will be prepared to reevaluate the medication, which patient receive unnecessary medication and what the determinants for a successful attempt to stop the medication, will be of enormous value.

Study objective

The aim of this project is to evaluate how many patients use medication for primary prevention of cardiovascular disease, how many patients are willing to be reevaluated and how many patients receive unnecessary treatment according to the new guidelines for cardiovascular risk management. Furthermore, we want to know how many of these patients are willing to discontinue their medication and what the determinants play a role in this decision. The costs and benefits of the reevaluation and discontinuation of medication will be evaluated. Adverse events will be carefully monitored.

Study design

Phase 1:
With literature research and the help of the Department of Public Health and Primary Care we identified possible determinants for a successful discontinuation of preventive cardiovascular medication.(appendix A). With this we developed a registration form per patient. In this phase we will identify the patients, aged 25-75 years without previous cardiovascular disease and without diabetes who receive preventive cardiovascular medication. (appendix B).

Fase 2:
During 18 months the selected patients without previous cardiovascular disease and without diabetes who receive preventive cardiovascular medication will be invited for a consultation with the practice nurse. The practice nurse explains the aims of the study and hands out an information letter. If the patient agrees to a reevaluation, an informed consent will be signed and a new risk

profile will be made with a new risk score (see below). With this new risk score the practice nurse will reevaluate the necessity of preventive cardiovascular medication. If there is no increased risk for cardiovascular disease (<10%), the practice nurse will make an appointment for a consultation with the general practitioner. The practice nurse will fill in the registration form (two copies). One copy will be handed over to the general practitioner. During a subsequent consultation the general practitioner will discuss the result of the reevaluation with the patient and will propose to discontinue the medication according to a personalized protocol, developed in cooperation with the local pharmacist. The general practitioner fills in the rest of the registration form and returns this form to the practice nurse. An appointment for follow up will be made.

Adverse events:
Adverse events will be notified every two weeks to the monitoring commission. Members of the monitoring commission are: E.P. Walma MD PhD, general practitioner in Schoonhoven, and department of general practice in Rotterdam, H.G.L.M. Grundmeijer MD PhD, general practitioner in Diemen, and department of general practice in, Amsterdam Medical Center. The forms with adverse events will be sent to the members of the commission every two weeks. The information about the adverse event will be separated from the personal identifying data. Personal data will remain in the practice. A serious adverse event will be notified the same day. In case no serious adverse events occur in the first three months of the project, the forms will be sent once a month to the commission. Still, in case of a serious adverse event, this will be done the same day.

The monitoring commission evaluates which adverse events can be related to the discontinuation of the medication. When needed, the commission will advise to stop the project, guided by the incidence of adverse events and guided by the seriousness of the adverse events.

Estimation of the size of the research population.
Approximately 1200 patients use primary preventive cardiovascular medication. We estimate that approximately 300 patients will be offered to discontinue the medication after reevaluation of the cardiovascular risk.

Phase 3:
After the second phase, in cooperation with the department of Public Health and Primary care, the results will be analyzed and an end evaluation of the project will be presented in a scientific article.

New risk estimation

During the second phase, all patients will be seen by the practice nurse. He/she will make a new risk estimation based on the new guidelines for

cardiovascular risk management. She will follow the next criteria:
• In case of no anti-hypertensive treatment, the blood pressure will be measured and the systolic blood pressure value will be used for the risk estimation.
• In case of anti-hypertensive treatment, a systolic blood pressure of 180 mmHg will be used for the new risk estimation, unless the value of the systolic blood pressure at the start of the hypertensive treatment can be retrieved.
• In case of no cholesterol lowering medication, the total cholesterol/HDL-cholesterol ratio will be calculated and used in the new risk estimation.
• In case of cholesterol lowering medication, a total cholesterol/HDL-cholesterol ratio of 8 mmol/l will be used, unless the ratio at the start of the cholesterol lowering medication can be retrieved.

The estimated values can be somewhat arbitrary. The choice for these values is made in this way in order to prevent a false positive low risk. In addition, in case of a systolic blood pressure or a ratio higher than the chosen values, more diagnostic evaluation would have taken place, even according to previous guidelines.

Intervention

See study design

Study burden and risks

Patients will come to the practice once for a reevaluation. After this, a number of patients will come to the general practitioner for consultation to discuss discontinuation of medication. In case the patient decides to discontinue medication, a few more consultations will follow during the follow up (see protocol).

Contacts

Public
Leids Universitair Medisch Centrum

PO Box 9600
2300 RC Leiden
Nederland
Scientific
Leids Universitair Medisch Centrum

PO Box 9600

2300 RC Leiden
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

patients of 18 years and older who have used medication to lower the blood pressure or to lower cholesterol in the past 12 months and who are not known to have cardiovascular disease

Exclusion criteria

serious cognitive impairment

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2008
Enrollment:	300
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL21838.058.08