Onderzoek naar de kosten-effectiviteit van het stoppen van bloeddrukverlagers en/of cholesterolverlagers bij patiënten met een laag risico op hart- en vaatziekten in de huisartsenpraktijk.

No registrations found.

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

Summary

ID

NL-OMON29344

Source
Nationaal Trial Register

Brief title
ECSTATIC

Health condition

Hypertensie, hypercholesterolemie, hart- en vaatziekten.
Hypertension, hypercholesterolemia, cardiovascular disease.

Sponsors and support

Primary sponsor: LUMC - Leids Universitair Medisch Centrum
Afdeling Public Health en Eerstelijnsgeneeskunde
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

The primary outcome measure is the change in 10-year CVD risk according to the risk table from the guideline CVRM 2011.

Secondary outcome

Secondary outcome measures are quality of life (EQ-5D + VAS), health care costs, (CVD related) mortality, cardiovascular events and side effects related to withdrawal of medication or use of medication. Other outcome measures are related to modifiable risk factors, such as smoking behaviour (smoking behaviour questionnaire), physical activity (SQUASH), alcohol consumption, eating habits (Standard nutrition questionnaire of Dutch common health services), systolic blood pressure (SBP), ratio of total cholesterol/HDL-cholesterol (TC/HDL ratio) in blood, Body Mass Index (body weight and height), and waist circumference.

Study description

Background summary

Background of the study:

In the Netherlands, cardiovascular disease (CVD) is the leading cause of mortality in women, the second leading cause in man, and is associated with loss of quality of life and high costs for the society (www.nationaalkompas.nl). Primary health care plays an important role in the primary prevention of CVD.

In 2006, the former guidelines Hypertension and Cholesterol of the Dutch College for General Practitioners (Nederlands Huisarts Genootschap (NHG)) were replaced by a combined guideline Cardiovascular Risk Management (CVRM), which is recently revised (2011). At the time, the transition of management of patients treated for hypertension and/or hypercholesterolemia according to the former guidelines Hypertension and Cholesterol into the guideline Cardiovascular Risk Management, was not part of this new guideline. The former guidelines recommended lower thresholds for the start of preventive medication in patients. Therefore, there are probably many patients unnecessarily treated with antihypertensive medication and/or lipid-lowering drugs according to the guideline CVRM 2011. This study will evaluate a medication withdrawal policy in these patients and will be carried out in collaboration with the Dutch College of General Practitioners (NHG). The NHG facilitates implementation of the study findings into routine clinical practice.

Objective of the study:

The general aim of this project is to evaluate the effectiveness, safety and costs of a medication withdrawal policy compared to usual care in general practice in patients who are currently treated for hypertension and/or hypercholesterolemia, but do not need pharmacological therapy according to the guideline CVRM 2011.

Study design:

This study employs a cluster randomised controlled non-inferiority trial in general practice, using a complete-double-consent design. The primary endpoint for effectiveness has been chosen at 12 months and for safety and costs at 24 months.

Study population:

The study population consists of patients, aged 40 to 70 years, with a 10-year risk of fatal or non-fatal CVD (10-year CVD risk) <17%, who received antihypertensive medication and/or lipid-lowering drugs during the last year for hypertension and/or hypercholesterolemia, and do not need pharmacological treatment according to the guideline CVRM at re-evaluation. Based on the pilot study of Van Duijn et al. we expect 10 included patients per practice. Therefore, about 46 general practices will provide the 464 individuals needed for this study. Patients with CVD are excluded.

Intervention:

The general practitioners (GPs) of the practices in the intervention group will actively withdraw medication in patients who do not need pharmacological treatment according to the guideline CVRM 2011.

GPs will receive a half-day training program, consisting of a general introduction about the guideline CVRM 2011, with special attention to primary prevention of CVD, and withdrawal of medication in patients without an indication for medication according to this guideline.

Study objective

Guidelines in the field of primary prevention of cardiovascular disease (CVD) are regularly revised. The thresholds for recommendation of pharmacological treatment differ between the old and new guidelines. Re-evaluation of a patient's need for pharmacological treatment is not part of the guidelines. A pilot study showed that many patients are unnecessarily treated and that withdrawing their medication is safe.

We expect that withdrawal preventive medication in patients who do not need pharmacological treatment according to the latest guideline Cardiovascular

Riskmanagement, is safe, cost-effective.

Study design

The primary outcome measure will be assessed at 0, 3 and 12 months.

Secundary outcome measures will be assessed at 0, 3, 6, 12, 24 months.

Intervention

The general practitioners (GPs) of the practices in the intervention group will actively withdraw medication in patients who do not need pharmacological treatment according to the guideline CVRM 2011.

GPs will receive a half-day training program, consisting of a general introduction about the guideline CVRM 2011, with special attention to primary prevention of CVD, and withdrawal of medication in patients without an indication for medication according to this guideline.

Contacts

Public
Leids Universitair Medisch Centrum
Afdeling Public Health en Eerstelijnsgeneeskunde (V6-74)
Postbus 9600
Clare H. Luymes
Leiden 2300 RC
The Netherlands
+31 (0)71 5268420
Scientific
Leids Universitair Medisch Centrum
Afdeling Public Health en Eerstelijnsgeneeskunde (V6-74)
Postbus 9600
Clare H. Luymes
Leiden 2300 RC
The Netherlands
+31 (0)71 5268420

Eligibility criteria

Inclusion criteria

1. Men and women aged 40 to 70 years;

2. Prescription of antihypertensive medication and/or lipid-lowering drugs for hypertension and/or hypercholesterolemia during the last 12 months (using ATC codes: C02, C03, C07, C08, C09, C10).

Exclusion criteria

1. Cardiovascular disease (ICPC codes: K74, K75, K76, K89, K90.03, K91, K92.01 and K99.01);

2. Use of platelet aggregation inhibitors (heparin excluded) (ATC code: B01AC);

3. Use of antihypertensive medication for another reason than prevention of CVD;

4. Familial hypercholesterolemia/lipidemia (ICPC code: T93.04);

5. Patients with a current SBP >180 mmHg, or a SBP >180 mmHg before the start of medication;

6. Patients with a current TC/HDL ratio >8, or a TC/HDL ratio >8 before the start of medication;

7. Patients with a 10-year CVD risk >16%;

8. 10-year CVD risk of 10-16% who need pharmacological treatment according to the guideline CVRM 2011.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2012
Enrollment:	464
Type:	Actual

Ethics review

Positive opinion

Date:	20-06-2012
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	NL3332
NTR-old	NTR3493
Other	METC Leiden / ZonMw : P12.095 / 50-51515-98-170;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A