Cost-effectiveness of an active withdrawal of medication policy versus usual care in patients currently treated for hypertension and/or hypercholesterolemia: a cluster-randomised controlled non-inferiority trial in general practice

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

Summary

ID

NL-OMON39214

Source
ToetsingOnline

Brief title
ECSTATIC

Condition

- Cardiac disorders, signs and symptoms NEC
- Central nervous system vascular disorders
- Vascular hypertensive disorders

Synonym
high blood pressure, high cholesterol, hypercholesterolemia, Hypertension

Research involving
Human

Sponsors and support

Primary sponsor: Zorgonderzoek Nederland (ZON)
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Cardiovascular disease, Guidelines, Medication withdrawal, Prevention

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), (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

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.

Study objective

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.

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 burden and risks

Patients will be re-evaluated by a blinded research nurse after randomisation has taken place. Baseline measurements are performed simultaneously. After re-evaluation and baseline measurements patients are asked to fill in a 45-minute questionnaire package. The same package is completed at 3 and 12 months. In addition, after 6 and 24 months they are asked to complete a cost-questionnaire and EQ-5D + VAS.
After re-evaluation and baseline measurements, the research nurse will examine the patients at 3, and 12 months, which will take about 30 minutes. Every examination a venous blood sample will be taken.
In general practices allocated to the usual care group, patients will be given the usual care.
The GPs in the intervention group will actively withdraw medication in the participating patients. Based on a previous report of a relapse of high blood pressure in the case of withdrawal(2;7-10), an individual follow-up will take place of 1-3 visits, which involves registration of side effects of withdrawal and measuring blood pressure, and serum lipid levels.

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 40 to 70 years;
• 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

• Cardiovascular disease (ICPC codes: K74, K75, K76, K89, K90.03, K91, K92.01 and K99.01);
• Use of platelet aggregation inhibitors (heparin excluded) (ATC code: B01AC);
• Use of antihypertensive medication for another reason than prevention of CVD;
• Familial hypercholesterolemia/lipidemia (ICPC code: T93.04);
• Patients with a current SBP >180 mmHg, or a SBP >180 mmHg before the start of medication;
• Patients with a current TC/HDL ratio >8, or a TC/HDL ratio >8 before the start of medication;
• Patients with a 10-year CVD risk >16%
• 10-year CVD risk of 10-16%, based on the 2011 risk table, in combination with at least one additional major risk-increasing factor;
• 10-year CVD risk of 10-16%, based on the 2011 risk table, in combination with two or more additional minor risk-increasing factors;
• 10-year CVD risk of 10-16%, based on the 2011 risk table, in combination with one additional minor risk-increasing factor and an SBP >140 mmHg and/or LDL >2.5 mmol/L.

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:	Recruitment stopped
Start date (anticipated):	07-11-2012
Enrollment:	464
Type:	Actual

Ethics review

Approved WMO Date:	11-06-2012
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	16-10-2012
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	08-11-2012
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	12-12-2012
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	08-01-2013
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	31-01-2013
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	03-04-2013

Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	01-05-2013
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	21-05-2013
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	01-07-2013
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	02-09-2013
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	13-11-2013
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	09-12-2015
Application type:	Amendment
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	NL40551.058.12