A randomised placebo-controlled trial of fixed-dose combination medication in people at raised risk of cardiovascular disease

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To measure the efficacy (change in systolic blood pressure and LDL cholesterol) and tolerability of a polypill in individuals with raised risk of a cardiovascular event.

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

Summary

ID

NL-OMON33869

Source
ToetsingOnline

Brief title
PILL pilot

Condition

- Coronary artery disorders
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
cardiovascular, hypertension

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cardiovascular, Framingham risk, Poly pill

Outcome measures

Primary outcome

To assess the efficacy (systolic blood pressure, LDL cholesterol) and

tolerability (the proportion who withdraw from trial treatment).

Secondary outcome

Treatment adherence (measured by pill count), diastolic blood pressure, total

cholesterol, HDL cholesterol, total cholesterol:HDL cholesterol ratio, non HDL

cholesterol, triglycerides, frequency of switching to open-label treatment,

estimated CVD risk, serious adverse events and all adverse events.

Study description

Background summary

One of the most hotly debated issues in cardiovascular disease (CVD) research is whether a *polypill* (a new combination cardiovascular medication containing aspirin and agents to lower blood pressure and cholesterol) can really reduce CVD by three-quarters or more. To assess this reliably will require a long term clinical trial of many thousands of participants. This protocol is for a pilot trial that will assess the efficacy and tolerability of the polypill.

Study objective

To measure the efficacy (change in systolic blood pressure and LDL cholesterol) and tolerability of a polypill in individuals with raised risk of a cardiovascular event.

Study design

Randomised, placebo-controlled, parallel-group trial (n=400)

Intervention

Eligible individuals willing to participate in the trial will be randomised to 12 weeks treatment with the polypill or to an identical matching placebo:
* Polypill: aspirin 75mg, simvastatin 20mg, lisinopril 10mg, hydrochlorothiazide 12.5mg.
* Placebo: identical matching placebo.
Both groups will also receive information about smoking cessation (if applicable) and how to follow a healthy heart diet. They will be advised to increase physical activity and lose weight if needed.

Study burden and risks

Measurements:
None of the study measures are dangerous. Routine blood samples taken may be associated with some bruising, discomfort and local irritation. There is also a small risk of infection whenever the skin is broken by a needle.

Medication:
The polypill combination cardiovascular medication will be an unapproved medication. However all the ingredients of the polypill combinations used in the trial are well known medicines with well established efficacy and safety profiles.

Although all the drugs in the polypill have been used for many years there are possible risks that the polypill or placebo may cause side effects. These are generally mild and infrequent and are usually resolved immediately by stopping the medication. Side effects of the components of the polypill can include low blood pressure, dizziness, headache, nausea, mild stomach pain, heartburn, ulceration, abdominal pain, constipation, flatulence, bleeding, gout, cough, fatigue, liver problems, and muscle pain, tenderness or weakness. As with any medication, an allergic reaction is possible such as skin rash, itching, difficulty breathing or swelling of the face, but this is quite rare.

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

Adults (> 18 years) with a cardiovascular disease (CVD) risk over 5 years of at least 7.5%, determined by the Framingham risk function (Anderson, 1991) using data on age, gender, blood pressure, total cholesterol, HDL cholesterol, diabetes status and cigarette smoking status.

Exclusion criteria

Clear indication for antiplatelet, blood pressure lowering or cholesterol lowering medications. This includes: current treatment with blood pressure or cholesterol lowering medicines, diabetes mellitus, existing CVD, or individuals with LDL cholesterol, systolic blood pressure or estimated CVD risk values above those recommended for treatment by local guidelines.

Study design

Design

Study phase:	2
Study type:	Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-10-2008
Enrollment:	105
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	nvt
Generic name:	aspirin 75 mg, simvastatin 20 mg, lisinopril 10 mg, hydrochlorthiazide 12.5 mg

Ethics review

Approved WMO Date:	20-12-2007
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	11-03-2008
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	09-09-2008
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	25-11-2008

Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	21-04-2009
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	12-05-2009
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	04-08-2009
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	22-09-2009
Application type:	Amendment
Review commission:	METC NedMec

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
Other	ACTRN012607000099426
EudraCT	EUCTR2007-002466-35-NL
CCMO	NL20733.041.07