HEART OUTCOMES PREVENTION EVALUATION (HOPE) - 3

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The HOPE-3 trial will evaluate the effects of lipid modification with rosuvastatin and of blood pressure lowering with candesartan/hydrochlorothiazide (HCT) and their combination in a wide range of middle aged people, who are at average risk for...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON33902

Source
ToetsingOnline

Brief title
HEART OUTCOMES PREVENTION EVALUATION (HOPE) - 3

Condition

- Other condition

Synonym
Cardiovascular disease

Health condition

Arteriële vaatziekten (atherosclerotisch vaatlijden)

Research involving
Human

Sponsors and support

Primary sponsor: Population Health Research Institute (PHRI)
Source(s) of monetary or material Support: Astra Zeneca,De producent van de gebruikte geneesmiddelen;AstraZeneca;heeft eenmalig een subsidie verleend aan het PHRI. De verantwoordelijkheid en de uitvoering van het onderzoek berusten geheel bij het PHRI.

Intervention

Keyword: average CVD-risk patients, double blind, outcome study, Rosuvastatin and/or Atacand Plus

Outcome measures

Primary outcome

The composite of CV death, non-fatal MI, non-fatal stroke, resuscitated cardiac

arrest, heart failure and coronary arterial revascularizations with objective

evidence of ischemia.

Secondary outcome

Secondary Efficacy Outcomes:

· The composite of CV death, non-fatal MI and non-fatal stroke;

· Total mortality

Tertiary Efficacy Outcome:

· Renal dysfunction (end-stage renal disease requiring dialysis or

transplantation, doubling of serum creatinine, development of microalbuminuria

or proteinuria).

Other Efficacy Outcomes:

· New diagnosis of diabetes mellitus;

· Other ischemic events (transient ischemic attack, intermittent claudication,

non-coronary revascularization).

· Cognitive decline will be evaluated in participants ³ 70 years

· Erectile dysfunction in men.

Study description

Background summary

Cardiovascular disease (CVD) is the major cause of death and disability worldwide and most events are potentially preventable. Most previous studies have evaluated therapies in high-risk patient subsets, such as those with existent CVD and/or those with substantial elevations in risk factors. Clinical trials have demonstrated that cholesterol and blood pressure levels can be effectively and safely lowered with statins and combination blood pressure lowering drugs and that these therapies can lower CV risk in high-risk people. However, there are only limited data in people at average risk.
The approach to CV prevention in people at average risk, who constitute the majority of individuals who develop CVD, remains uncertain. Epidemiological studies indicate that elevated cholesterol and blood pressure are major risk factors and account for a substantial proportion (>70%) of the population attributable risk for CVD. The relationships between cholesterol and blood pressure respectively to CV risk are continuous, extending well below average (*normal*) levels.

Study objective

The HOPE-3 trial will evaluate the effects of lipid modification with rosuvastatin and of blood pressure lowering with candesartan/hydrochlorothiazide (HCT) and their combination in a wide range of middle aged people, who are at average risk for vascular events.

Study design

During a 4-week run-in phase, eligible study participants will receive single-blind therapy with rosuvastatin 10 mg and candesartan/HCT 16/12.5 mg daily. Individuals with high adherence, who tolerate these therapies will be randomized to double blind study therapy consisting of rosuvastatin 10 mg/day vs. rosuvastatin placebo and to candesartan/HCT 16/12.5 mg/day vs. candesartan/HCT placebo utilizing a 2 x 2 factorial design. Follow-up will occur 6 weeks after randomization, at 6 months and thereafter every 6 months for an average of at least 5 years.

Intervention

see study design

Study burden and risks

The patients will visit their general practioner max. 15 times (+ one telephone call between visit 2 and 3). After the study the patients will be followed for another 10 years (one yearly contact for major clinical events).
Venipuncture will be done 9-times. Bruises may evolve.
The study is expected to identify safe and effective CV prevention strategies which could substantially reduce the risk of CVD in large proportions of the adult population worldwide.

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

Women aged >60 with at least two additional CV risk factors and men > 55 with at least one additional CV risk factor:
-Waist/hip ratio > 0.9 in men and > 0.85 in women
-History of current or recent smoking (regular tobacco use within 5 years)
-Low HDL cholesterol (<1 mmol/L in men and <1.3 mmol/L in women)
-Dysglycemia
-Renal dysfunction
-Family history of premature CHD in first degree relatives;Provision of Informed Consent;Also see page 16 of the Study Protocol

Exclusion criteria

-Documented clinically manifest atherothrombotic CVD
-Clear indication for statin and/or ARB or ACE inhibitor and/or thiazide diuretic therapy
-Clear contra indication for statin and/or ARB or ACE inhibitor and/or thiazide diuretic therapy
-Symptomatic hypotension
-Other safety/contra-indications: i.e.: Chronic liver disease; inflammatory muscle disease; severe renal impairment; concurrent treatment with cyclosporine or a condition likely to result in organ tranplantation and the need for cyclosporine
-concurrent treatment with a statin, fibrate, angiotensin receptor blocker, ACE nhibitor or a thiazide diuretic
-Other serious medical illness likely to interfere with study participation or with the ability to complete the trial
-mental disturbances, which could impair the ability to provide informed consent and to adhere to the trial procedures
-concurrent us of an experimental pharmacological agent;Also see page 16 and 17 of the Study Protocol

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)

Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	30-11-2007
Enrollment:	400
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Atacand Plus
Generic name:	Candesartan/Hydrochlorothiazide
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	Crestor
Generic name:	Rosuvastatine
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	18-08-2008
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	27-01-2009
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	11-03-2009
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	17-06-2010
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-12-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-06-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
EudraCT	EUCTR2007-001493-91-NL
CCMO	NL18820.018.07