Effects of Temporary Inhibition of the Renin-Angiotensin System on future blood pressure and hypertensive organ damage in young prehypertensive adults * TIResiAS

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To test the hypothesis whether treatment with an ACE inhibitor in young prehypertensive adults reduces blood pressure 2 years after cessation of active treatment and to determine whether this treatment can reduce left ventricular mass and...

Ethical review	Approved WMO
Status	Pending
Health condition type	Vascular hypertensive disorders
Study type	Interventional

Summary

ID

NL-OMON30810

Source
ToetsingOnline

Brief title
Temporary Inhibition of the Renin Angiotensin System - TIResiAS study

Condition

- Vascular hypertensive disorders

Synonym
elevated blood pressure, hypertension

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Zon-MW;programma innovatieve preventie

Intervention

Keyword: Hypertension Angiotensin-Converting_Enzyme_Inhibitors Preventive_Therapy Randomized_Controlled_Trials

Outcome measures

Primary outcome

Blood pressure 2 years after cessation of active treatment as evidenced by

differences in 24 hour ambulatory blood pressure measurements.

Secondary outcome

Differences in left ventricular mass and microalbuminuria 2 years after active

treatment.

Study description

Background summary

Blood pressure is linearly related with cardiovascular risk.. A recent population based survey showed that 30% of persons with high normal blood pressure (BP 130-140/85-90 mmHg) developed hypertension during 3 years follow-up. This was also accompanied by an increase in cardiovascular complications. Prevention or delaying hypertension by an early and temporary intervention in these high risk individuals is an interesting and probably cost effective therapeutic strategy. Recent experiments in spontaneous hypertensive rats (SHR) have shown that early and temporary inhibition of the renin-angiotensin system (RAS) results in a long term anti-hypertensive effect, also after cessation of treatment and prevents hypertensive organ damage. Possibly this is the case for humans. The hypothesis that temporary treatment of prehypertensive persons results in future blood pressure reduction in humans is currently being tested in a multi-centre trial elsewhere. The design of this study poses several limitations. These issues will be overcome in the TIResiAS study.

Study objective

To test the hypothesis whether treatment with an ACE inhibitor in young prehypertensive adults reduces blood pressure 2 years after cessation of active treatment and to determine whether this treatment can reduce left ventricular mass and microalbuminuria.

Study design

Multi-centre double blind randomized placebo controlled trial.

Intervention

Individuals are randomized to receive either lisinopril 10mg daily for three weeks followed by lisinopril 20mg daily or matched placebo for a period of one year. This is followed by two years of regular blood pressure monitoring.

Study burden and risks

Study burden: 4 visits of 3 hours, 16 visits of 15-30 minutes, 4 times 24 hours ambulatory blood pressure monitoring and 24 hours urine collection. The total study takes 3 years of which 1 year of daily medication intake. ACE inhibitors are save and effective antihypertensive drugs, side effect include a non-productive cough (estimated prevalence 5-10%), deterioration of renal function, hyperkalemia, (orthostatic) hypotension and angioedema (prevalence <0.4 %). All side effects will be closely monitored, stop criteria have been clearly defined in the study. Lisinopril may cause damage to the unborn fetus in the 2nd
and 3rd trimester of pregancy. At the start of the study pregnancy will be excluded by a pregnancy test. Women participating in this study will be advised to use reliable contraceptives during the active treatment period and advised to contact the study doctor in case the menstrual period is more than 2 weeks overdue for a pregnancy test. If study participants develop hypertension (BP >140/90 mmHg) antihypertensive therapy will be instituted according to standardized protocols, following present guidelines.

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

Included are persons aged 18-40 years with an average blood pressure of 130-139 systolic/below 90 mmHg diastolic and/or below 130 systolic/ 85-89 mmHg diastolic on 3 separate office visits with an interval of one week as measured by an automated blood pressure device (Omron M4).

Exclusion criteria

Excluded are persons with any (chronic) disease requiring medication or specialist treatment, patients with 3 or more risk factors according to current ESH guidelines, an elevated baseline serum glucose or elevated serum creatinine and females with a wish to become pregnant in the treatment period.

Study design

Design

Study phase:	4
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):	01-01-2007
Enrollment:	300
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	lisinopril tabletten
Generic name:	lisinopril
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	01-02-2007
Application type:	First submission
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	EUCTR2006-002964-24-NL
Other	ISRTCN aangevraagd
CCMO	NL11839.018.06