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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22745

Source
NTR

Brief title
TIResiAS

Health condition

Prehypertension, defined as an avarage office blood pressure of 130-139/85-89 mmHg.

Sponsors and support

Primary sponsor: Academic Medical Centre
Dept.Vascular Medicine
Meibergdreef 9
1105 AZ Amsterdam
The Netherlands
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Source(s) of monetary or material Support: ZonMw (innovative prevention)

Intervention

Outcome measures

Primary outcome

Differences in ambulatory blood pressure between lisinopril and placebo 2 years after cessation of active treatment compared to baseline.

Secondary outcome

Differences in left ventricular mass (index) and microalbuminuria between lisinopril and placebo 2 years after cessation of active treatment compared to baseline.

Study description

Background summary

Title
Effects of Temporary Inhibition of the Renin-Angiotensin System on future blood pressure and hypertensive organ damage in young prehypertensive adults – TIResiAS.
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.
Study population
Otherwise healthy volunteers aged 18-40 years with an average blood pressure of 130-139 systolic and/or 85-89 mmHg diastolic on 2 separate office visits with less than 3 risk factors for cardiovascular disease according to current ESH guidelines.
Excluded are subjects with previous antihypertensive treatment, any chronic disease requiring medication or specialist treatment, an elevated baseline serum glucose or elevated serum creatinine and women with a wish to become pregnant in the treatment period.
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.
Primary endpoint
Blood pressure 2 years after cessation of active treatment as evidenced by differences in 24 hour ambulatory blood pressure measurements.
Secondary endpoints

Differences in left ventricular mass and microalbuminuria 2 years after active treatment.

Study objective

Hypertension can be prevented, or substantially delayed, by a temporary and early anti-hypertensive intervention with an ACE inhibitor in persons at high risk for future hypertension and hypertension related complications.

Intervention

Individuals are randomized to receive either lisinopril 10mg daily for three weeks followed by a forced titration to lisinopril 20mg daily or matched placebo for a period of one year. This is followed by two years of close observation without active treatment.

Contacts

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Eligibility criteria

Inclusion criteria

Otherwise healthy persons aged 18-40 years with 3 cardiovascular risk factors or less and an average blood pressure of 130-139 systolic/below 90 mmHg diastolic and/or below 130

systolic/ 85-89 mmHg diastolic on 2 separate visits with an interval of 1 week and measured by a validated automatic blood pressure device.

Exclusion criteria

1. Previous antihypertensive treatment;
2. Any chronic use of prescribed oral medication except oral contraceptives;
3. An elevated baseline serum glucose (>7.0 mmol/L) or elevated serum creatinine(> 95 ummol/L for women and >110 ummol/L for men);
4. Women with a wish to become pregnant in the treatment period.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2007
Enrollment:	300
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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	NL880
NTR-old	NTR894
Other	: 06/307
ISRCTN	ISRCTN52222985

Study results