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

Submission date
26/02/2007

Recruitment status
No longer recruiting

Registration date
26/02/2007

Overall study status
Completed

Last Edited
26/03/2021

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.tiresiastrial.nl

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
06/307, NL880 (NTR894)

Study information

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

Acronym
TIResiAS

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

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised, placebo controlled, parallel group, double blinded, multicentre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Prehypertension

Interventions

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

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Lisinopril

Primary outcome measure
Differences in ambulatory blood pressure between lisinopril and placebo two years after cessation of active treatment compared to baseline.

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

Overall study start date
01/02/2007

Completion date
01/02/2011

Eligibility

Key inclusion criteria
Otherwise healthy persons aged 18 to 40 years with three 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 two separate visits with an interval of one week and measured by a validated automatic blood pressure device.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
300

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

Date of first enrolment
01/02/2007

Date of final enrolment
01/02/2011

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Medical Centre
Amsterdam
Netherlands
1105 AZ

Sponsor information

Organisation
Academic Medical Centre (AMC) (The Netherlands)

Sponsor details
Department of Vascular Medicine
P.O. Box 22660
Amsterdam
Netherlands
1100 DD

Sponsor type
Hospital/treatment centre

Website
http://www.amc.uva.nl/#http://www.amc.uva.nl/

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Research organisation

Funder Name
The Netherlands Organisation for Health Research and Development (ZonMw) (The Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		11/08/2007	26/03/2021	Yes	No