A follow-up study of the Discontinuation of ANtihypertensive treatment in the Elderly (DANTE) study Leiden

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To assess the association between baseline blood pressure and change in neurocognitive functioning after four years, and to assess whether baseline MRI phenotypes are predictive for changes in neurocognitive functioning after four years in the DANTE...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON43484

Source
ToetsingOnline

Brief title
A follow-up study of the DANTE study Leiden

Condition

- Other condition
- Central nervous system vascular disorders
- Dementia and amnestic conditions

Synonym
Blood pressure and cognition

Health condition

depressie, apathie, dagelijks functioneren en kwaliteit van leven

Research involving

Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: NWO - Vici Prof. dr. S.A.R.B. Rombouts

Intervention

Keyword: Blood Pressure, Cognition, Cognitive impairment, Elderly, Psychological functioning

Outcome measures

Primary outcome

The main study parameters are blood pressure, (domains of) cognitive

functioning, symptoms of depression and apathy, general daily functioning and

quality of life.

Secondary outcome

Secondary study parameters are antihypertensive medications, occurrence of

(cardiovascular) events, as well as (new) medical diseases such as dementia,

and death.

Study description

Background summary

High blood pressure at mid-life is a well-known risk factor for cognitive decline in old age. Nevertheless, the effect of late-life blood pressure on cognition remains ambiguous. Observational studies suggested that in old age a lower rather than a higher blood pressure is associated with an increased risk of cognitive decline .The DANTE Study Leiden, was a community-based randomized controlled trial designed to explore whether discontinuation of antihypertensive treatment for four months would improve cognitive and psychological functioning. In the DANTE population (n=398) of older persons aged 75 years and over, blood pressure as well as cognition, symptoms of depression and apathy, general daily functioning and quality of life were

assessed at baseline and at four-month follow-up. The results of the DANTE study Leiden indicated that discontinuation of antihypertensive treatment indeed increased the blood pressure. However, the four-month discontinuation of antihypertensive treatment did not improve cognitive, psychological, and general daily functioning.

In a subset (n=220) of the DANTE population, MRI was performed at baseline. These data showed that in persons with a relatively low BP, specific features of neurodegeneration were present, such as increased subcortical atrophy and a diminished microstructural integrity. On baseline, these changes were cross-sectionally associated with a lower cognitive performance. Interestingly, similar neurodegenerative changes, were predictive for a steeper decline in cognitive ability in a slightly younger population (mean age 73y). The hypothesis of the present research proposal is that older persons with a relatively low blood pressure at baseline will show a steeper decline in neurocognitive functioning at four-year follow up than persons with a relatively high BP at baseline. We also think that certain MRI phenotypes, including subcortical atrophy and a diminished microstructural integrity, are predictive for a decline in cognitive functioning after four years.

Study objective

To assess the association between baseline blood pressure and change in neurocognitive functioning after four years, and to assess whether baseline MRI phenotypes are predictive for changes in neurocognitive functioning after four years in the DANTE population.

Study design

Observational follow-up study

Study burden and risks

Persons who wish to participate will receive a one-time home visit. Within a maximum of 90 minutes the researcher will measure blood pressure and assess neurocognitive functioning, general daily functioning and quality of life using above mentioned tests and questionnaires. There are no risks associated with participation in this study. The burden associated with participation is mostly the demands on the subjects* time and energy.

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

This is a follow-up study of the DANTE study Leiden. Therefore, inclusion criteria are:
(1) previous participation in the DANTE study Leiden.
(2) agreement on the informed consent form of the DANTE study Leiden that the subject may be contacted for future studies associated with the DANTE study Leiden.
(3) a confirmation of the subjects* general practitioner that the subject is able to participate in the follow-up study.

Exclusion criteria

Judgement by the subject*s general practitioner that the subject is not able to participate in the follow-up study

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-05-2016
Enrollment:	250
Type:	Actual

Ethics review

Approved WMO

Date:	20-04-2016
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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
CCMO	NL56159.058.16