Effects of temporary discontinuation of antihypertensive treatment in older patients with cognitive impairment: A randomised controlled trial.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26485

Source
Nationaal Trial Register

Brief title
DANTE-Leiden

Health condition

antihypertensive therapy - cognitive functioning - elderly

Sponsors and support

Primary sponsor: Leiden University Medical Center
Source(s) of monetary or material Support: ZonMW

Intervention

Outcome measures

Primary outcome

Primary outcome is the change in the compound cognitive score between baseline and

follow-up at 4 months after randomisation (At baseline and at 4 months follow-up, from all patients a number of cognitive measurements will be obtained: MMSE, for global cognitive functioning, Stroop-Colour Word Test (SCWT) and Trail Making Test (TMT) for executive functioning, 15-Word Verbal Learing Test (15-WVLT) and Visual Association Test (VAT) for (immediate and delayed) verbal and picture memory, and Letter-Digit Substitution Test (LDST) for psychomotor speed. The six aforementioned cognitive tests will be combined in a cognitive compound score.

Secondary outcome

At baseline and at 4 months follow-up, moreover, the Neuropsychiatric Inventory (NPI) will be carried out for, among others, assessment of depression and apathy (Cummings et al., 1994). Furthermore, general daily functioning will be assessed with the Groningen Activity Restriction Scale (GARS) (Kempen et al., 1996) and quality of life with Cantril's ladder (Cantril, 1965). Secondary outcome measures are the change in the four separate cognitive domains (global cognitive functioning, executive functioning, (immediate and delayed) memory and psychomotor speed; the change in depressive symptoms and apathy as assessed with the NPI; physical functioning as assessed with the GARS, and quality of life according to Cantril's ladder.

Study description

Background summary

Blood pressure reduction in older people may lead to hypoperfusion, especially in patients with cerebral small vessel disease, resulting in increased mental health problems like cognitive impairment, depression, and apathy. In this study we will assess whether temporary discontinuation of antihypertensive therapy in mildly cognitively impaired older patients on antihypertensive treatment improves cognitive and psychological functioning.

Study objective

To assess whether temporary discontinuation of antihypertensive therapy in mildly cognitively impaired older patients on antihypertensive treatment improves cognitive and psychological functioning.

Study design

Baseline measurement and 4 months of follow-up.

Intervention

Patients will be randomized to either continuation (n=200) or discontinuation (n=200) of

antihypertensive treatment. Discontinuation of antihypertensive medication by patients' own general practitioner may vary from abrupt and complete discontinuation to gradual and partial discontinuation, with a 20 mmgHg increase in systolic blood pressure as target and 180 mmHg as maximum systolic blood pressure.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age ≥ 75 years;

2. Current antihypertensive treatment;

3. Current systolic blood pressure < 160 mmHg;

4. Mini-Mental State Examination (MMSE) score ≥ 21 and ≤ 27.

Exclusion criteria

1. A history of myocardial infarction, stroke, coronary reperfusion procedures (CABG/PCI) < 3 years;

2. Heart failure requiring antihypertensive medication.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2011
Enrollment:	400
Type:	Anticipated

Ethics review

Positive opinion

Date:	29-03-2011
Application type:	First submission

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	NL2300
NTR-old	NTR2829
Other	METC LUMC / ZonMw : P10.208 / 40-41600-98-9014;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A