Discontinuation of ANtihypertensive Treatment in Older people with dementia living in a Nursing home

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To assess whether discontinuation of antihypertensive treatment in nursing home residents with dementia a) reduces NPS and improves quality of life; b) improves general daily functioning and cognitive functioning; c) reduces psychotropic medication...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Dementia and amnestic conditions
Study type	Interventional

Summary

ID

NL-OMON50258

Source
ToetsingOnline

Brief title
Danton Study

Condition

- Dementia and amnestic conditions

Synonym
dementia, neuropsychiatric symptoms

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: ZonMW programma Memorabel

Intervention

Keyword: anti-hypertensives, dementia, deprescibing, neurospychiatric symptoms

Outcome measures

Primary outcome

The co-primary outcome measures are the differences in change of scores between 0 and 4 months on the Neuropsychiatric Inventory - Nursing Homes (NPI-NH) and quality of life (Qualidem).

Long-term effects on primary and secondary outcomes will be analysed over 8 months

Secondary outcome

Secondary outcome measures include NPS registered in the medical records, care dependency, cognitive function, general daily functioning, care-related quality of life, orthostatic hypotension, incident falls, and psychotropic medication use.

Long-term effects on primary and secondary outcomes will be analysed over 8 months. In addition, cost-effectiveness will be evaluated.

Study description

Background summary

Neuropsychiatric symptoms (NPS) are very common in people with dementia and severely affect quality of life and general daily functioning and hamper optimal care. They are a burden for carers and a main reason for institutionalisation. Recent studies found that hypoperfusion of the brain,

hypothesised to be a result of impaired autoregulation, is related to NPS. Since antihypertensive treatment is associated with hypoperfusion of specific brain areas, increasing the blood pressure by discontinuing antihypertensive treatment is a promising treatment option for NPS, especially since 50% of the nursing home residents with dementia use antihypertensive treatment.

Study objective

To assess whether discontinuation of antihypertensive treatment in nursing home residents with dementia
a) reduces NPS and improves quality of life;
b) improves general daily functioning and cognitive functioning;
c) reduces psychotropic medication use, falls, care dependency and caregiver burden;
and
d) is safe regarding cardiovascular events.

Study design

Study design: Randomized open-label, single-blind controlled clinical trial.

Intervention

Randomization to discontinuation (n=246) or continuation (n=246) of antihypertensive treatment during 8 months. Discontinuation of antihypertensive treatment aims to achieve a systolic blood pressure increase of 20 mmHg using a drug-specific discontinuation algorithm.

Study burden and risks

Assessments of NPS with the NPI-NH, quality of life, dementia severity, cognitive functioning, care dependency and general daily functioning will be done at the nursing home both at baseline and at 4 and 8 months. Most questionnaires will be filled out by professional and informal caregivers of the patients to get information by proxy.

Patients in both study arms will continue to receive blood pressure measurements during follow-up after a stable blood pressure has been reached. This will be done for safety reasons in the intervention arm and to make both study arms as similar as possible also in the control arm. Patients in the intervention arm will be put on their original antihypertensive medication when diastolic blood pressure exceeds 120 mmHg or systolic blood pressure exceeds 200 mmHg (180 mmHg for participants with diabetes mellitus or those who had had a cardiovascular event >12 months ago) or an increase in systolic blood pressure of 60 mmHg or greater relative to baseline. Moreover, all cardiovascular events during the study will be closely monitored to prevent an

increase in cardiovascular events in the intervention group. A Data Safety and Monitoring Board (DSMB) will be installed for monitoring of the safety data (cardiovascular events).

This study will not interfere with standard care, diagnostics and treatment (other than antihypertensive treatment) for patients with dementia.

Given the future rise in the number of older people with dementia and NPS in our society, the impact of this trial will be substantial when this trial demonstrates that NPS can be alleviated and quality of life can be improved by discontinuation of antihypertensive treatment. Since NPS hamper optimal care and are a serious burden for caregivers, this study will not only have an impact on dementia patients, but also on caregivers and nursing staff.

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

Eligible to participate in this study, a subject must meet all of the following criteria:
• being admitted in nursing home
• have a diagnosis of moderate to severe dementia according to the Reisberg Global Deterioration Scale (score 5-6-7)
• are currently on antihypertensive treatment with a calcium antagonist, diuretic, ACE-inhibitor, beta-blocker or angiotensin-II-receptor blocker prescribed for hypertension
• have a systolic blood pressure <=160mmHg (average of two last blood pressure measurements)

Exclusion criteria

An potential subject who meets any of the following criteria will be excluded from participation:
• recent (<12 months) history of myocardial infarction, stroke, coronary reperfusion procedures (CABG/PCI)
• heart failure NYHA class III or IV
• current angina pectoris
• have a life-expectancy less than 4 months.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-11-2018

Enrollment:	492
Type:	Actual

Ethics review

Approved WMO Date:	15-10-2018
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	07-03-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	05-06-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	04-07-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	24-12-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO
Date: 13-03-2020

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO
Date: 06-06-2020

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO
Date: 06-07-2020

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO
Date: 02-10-2020

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO
Date: 04-12-2020

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO
Date: 31-01-2021

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO Date:	18-06-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 27766
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL65719.058.18
OMON	NL-OMON27766