‘Discontinuation of antihypertensive treatment in older people with dementia living in a nursing home.’

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27766

Source
Nationaal Trial Register

Brief title
DANTON study

Health condition

Older adults, Antihypertensive treatment, Dementia, Nursing home, Neuropsychiatric symptoms

Sponsors and support

Primary sponsor: Leiden University Medical Center (LUMC)
Source(s) of monetary or material Support: ZON-MW, The Netherlands Organization for Health Research and Development

Intervention

Outcome measures

Primary outcome

The co-primary outcomes of this study are the change in neuropsychiatric symptoms in

various domains measured with the Neuropsychiatric Inventory–Nursing Homes (NPI-NH) and quality of life measured with Qualidem between baseline and 4 month follow-up after randomisation.

Secondary outcome

- NPS registered in the medical nursing home records during the study period, concomitant psychotropic medication use, psychosocial interventions started for NPS

- apathy (abbreviated Apathy Evaluation Scale)

- general daily functioning (Katz Index of Independence in activities of daily living), care dependency (Care Dependency Scale)

- cognitive function (7-category Minimum Data Set Cognitive Performance Scale)

- orthostatic hypotension

- number of falls

- caregiver burden (formal and informal caregivers, CarerQoL-7D)

Study description

Background summary

Rationale: Neuropsychiatric symptoms (NPS) are very common in people with dementia, severely affect quality of life and general daily functioning and hamper optimal care. They are a burden for caregivers 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.

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: Randomized controlled clinical trial.

Study population/eligibility criteria: Residents from nursing homes can participate if they (1) have a diagnosis of moderate-severe dementia, (2) are on antihypertensive treatment, and (3) have a systolic blood pressure <=160mmHg. Older adults will be excluded if they have heart failure NYHA class III or IV, recent (<12 months) history of myocardial infarction, stroke, coronary reperfusion procedures (CABG/PCI), or have a life-expectancy less than 4 months.

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.

Main study parameters/endpoints: 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. Secondary outcome measures include NPS registered in the medical records, apathy, 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.

Benefit and group relatedness: 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 it 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.

Study objective

Overarching aim of the present project is to study the effects of discontinuation of antihypertensive medication in older patients with dementia. We hypothesize that increasing blood pressure by discontinuation of antihypertensive treatment would reduce neuropsychiatric symptoms (NPS) and improves quality of life in nursing home residents with moderate to severe dementia.

Study design

Baseline measurement, 4 months follow-up and 8 months follow-up

Intervention

Patients will be randomized to either continuation (n=246) or discontinuation (n=246) of antihypertensive treatment. In participants randomized to the intervention group, their treating elderly care physician will actively withdraw antihypertensive treatment. The clinical responsibility for the aimed increase in blood pressure of 20 mmHg by (partial)

discontinuation of antihypertensive medications will be taken by the treating elderly care physician of the individual participant . Discontinuation of antihypertensive medication may vary from abrupt and complete discontinuation to gradual and partial discontinuation.

Contacts

Public
Leiden University Medical Center (LUMC)
Jonathan Bogaerts

071 526 86 40
Scientific
Leiden University Medical Center (LUMC)
Jonathan Bogaerts

071 526 86 40

Eligibility criteria

Inclusion criteria

- resident in a nursing home

- a diagnosis of moderate to severe dementia according to the Reisberg Global Deterioration Scale (score 5-6-7)

- currently on antihypertensive treatment with a calcium antagonist, diuretic, ACE-inhibitor, beta-blocker or angiotensin-II-receptor blocker prescribed for hypertension

- systolic blood pressure <=160mmHg (average of two last blood pressure measurements)

Exclusion criteria

- recent (<12 months) history of myocardial infarction, stroke, coronary reperfusion procedures (CABG/PCI)

- heart failure NYHA class III or IV

- current angina pectoris

- a life-expectancy less than 4 months

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2018
Enrollment:	492
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	25-10-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 50258
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7365
NTR-old	NTR7573
CCMO	NL65719.058.18
OMON	NL-OMON50258

Study results

Summary results
N/A