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

Gepubliceerd: 25-10-2018 Laatst bijgewerkt: 15-05-2024

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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27766

Bron
NTR

Verkorte titel
DANTON study

Aandoening

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

Ondersteuning

Primaire sponsor: Leiden University Medical Center (LUMC)
Overige ondersteuning: ZON-MW, The Netherlands Organization for Health Research and Development

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Leiden University Medical Center (LUMC)
Jonathan Bogaerts

071 526 86 40

Wetenschappelijk

Leiden University Medical Center (LUMC)
Jonathan Bogaerts

071 526 86 40

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-11-2018
Aantal proefpersonen:	492
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	25-10-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 50258
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A