Hypertensive treatment in older adults with vascular brain lesions: should we SPRINT faster?

No registrations found.

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

Summary

ID

NL-OMON24551

Source
Nationaal Trial Register

Brief title
SPRINT2017

Health condition

Hypertension

Cerebral Small Vessel Disease (CSVD)

Hypertensie

Cerebrale wittestofschade

Sponsors and support

Primary sponsor: VU University Medical Centre
Source(s) of monetary or material Support: Amsterdam CardioVascular Research Institute

Intervention

Outcome measures

Primary outcome

cerebral blood flow velocity

Secondary outcome

cognitive functioning, white matter lesions, orthostatic hypotension, dynamic cerebral autoregulatory capacity, CO2 responsiveness, experienced side effects, disability to reach assigned BP target

Study description

Background summary

Pilot trial testing the effect of intensive control (SBP ≤120 mmHg) versus conventional targets (SBP<140-150 mmHg) on cerebral blood flow velocity in older (≤ 65 yrs) hypertensive patients with cerebral small vessel disease. Secondary objectives are to test the effect of tight blood pressure control on cognitive functioning, degree of white matter lesions and unacceptable side-effects of antihypertensive drugs.

Study objective

To test if intensive control (SBP ¡Ü120 mmHg) decreases cerebral blood flow velocity compared to conventional targets (SBP<140-150 mmHg) in PB in patients with CSVD and hypertension.

Study design

baseline, after 4 months of follow-up

Intervention

intensive control (SBP ≤120 mmHg)

Contacts

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Eligibility criteria

Inclusion criteria

• ≥ 65 years of age

• High systolic blood pressure of 150-200mmHg based on the average of a daytime 24-hour BP (with or without taking antihypertensive medication)

• Cerebral small vessel disease (white matter lesions; Fazekas score ≥ 2) on MRI

Exclusion criteria

• Medical history of diabetes mellitus

• Experienced myocardial infarction within the past 12 months

• Medical history of stroke in the past 6 months or large (sub) cortical cerebral infarction on MRI

• Medical history of end stage heart failure (NYHA III-IV)

• Stage 4-5 kidney failure

• Diagnosed with dementia

• Life expectancy less than 1 year

• Unable to obtain an optimal window for TCD measurements during first visit at the outward patient clinic

• Significant stenosis (>70%) of the left of right common carotid artery

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):	30-09-2017
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date:	28-08-2017
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	NL6474
NTR-old	NTR6661
Other	METC VUmc : 2017.099

Study results