

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

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	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, CO<sub>2</sub> responsiveness, experienced side effects, disability to reach assigned BP target

## Study description

### Background summary

Pilot trial testing the effect of intensive control (SBP  $\leq$  120 mmHg) versus conventional targets (SBP < 140-150 mmHg) on cerebral blood flow velocity in older ( $\leq$  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  $\leq$  120 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  $\leq$  120 mmHg)

## Contacts

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## Eligibility criteria

### Inclusion criteria

- $\geq 65$  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  $\geq 2$ ) 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