# Transcranial color-coded duplex sonography in patients with cerebral venous thrombosis

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to evaluate the feasibility, time-course and association with clinical manifestations of the pulsatility index (PI) in patients with cerebral venous thrombosis.

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Central nervous system vascular disorders |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON40731

**Source**
ToetsingOnline

**Brief title**
TCCS in cerebral venous thrombosis

### Condition

- Central nervous system vascular disorders

**Synonym**
cerebral venous thrombosis

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum
**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** cerebral venous thrombosis, intracranial pressure, pulsatility index, transcranial color coded duplex sonography (TCCS)

## Outcome measures

### Primary outcome

Pulsatility index (PI)

o Change over time

o Correlation with clinical symptoms and outcome

### Secondary outcome

n/a

# Study description

### Background summary

Cerebral venous thrombosis (CVT) is a relatively uncommon form of stroke. The estimated incidence is 13 per million/year. CVT occurs in similar clinical circumstances as the more common conditions of leg-vein thrombosis and pulmonary embo¬lism, such as thrombophilia (acquired or genetic), pregnancy, oral contraceptives and in patients with hematological diseases or cancer. In addition, CVT can be the result of local conditions, such as head trauma, infections, and meningitis. Similar to deep vein thrombosis, the treatment of choice in CVT is heparin. The prognosis is generally good, especially compared to other types of stroke, although approximately 20% of patients remain disabled or die1.

Most patients with CVT have increased intracranial pressure (ICP) due to venous obstruction and impaired drainage of the cerebrospi¬nal fluid. Symptoms associated with intracranial hypertension are headache and impaired vision.2,3 In rare situations, severe intracranial hypertension may result in decreased cerebral perfusion and coma.
Although intracranial pressure is an important parameter in CVT, the ICP is rarely measured because it requires an invasive procedure (lumbar puncture or shunting procedure). All patients with CVT are treated with anticoagulation and therefore these invasive procedures carry the risk of hemorrhagic complications. A non-invasive method to measure the intracranial pressure in

patients with CVT would enable us to monitor the ICP, learn about the pathophysiology of the disease, its complications and prognosis and might provide a basis for future treatment decisions to reduce intracranial pressure.

Transcranial color- coded duplex sonography (TCCS) through the transtemporal acoustic window might be a good non-invasive tool for assessment of intracranial pressure. The pulsatility index (PI), a parameter calculated form TCCS derived flow velocities, has been found to be associated with intracranial pressure in various neurological conditions.4 The usefulness of PI has been studied most widely in traumatic brain injury. Although the strength of the association with ICP varies between studies, it seems that PI may be useful to monitor changes in intracranial pressure over time. Recently a case-report was published, demonstrating successful intracranial pressure monitoring with serial transcranial Doppler observations in a patient with CVT.5
Because assessment of PI with TCCS is a quick, easy and non-invasive tool which can be repeatedly performed, it is worth investigating its value in patients with CVT.

### Study objective

to evaluate the feasibility, time-course and association with clinical manifestations of the pulsatility index (PI) in patients with cerebral venous thrombosis.

### Study design

single centre, observational study

### Study burden and risks

There are no risks associated with participation to this study. Transcranial sonograpy is non-invasive and carries no risk. No extra visits to the hospital are needed for participation in this study. Therefore, the patient burden of participation is small.
Individual patients will not benefit from participation in this study.

## 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

diagnosed with cerebral venous thrombosis by CT-venography, MRI/MR-venography or conventional angiography
> 18 years

## Exclusion criteria

the presence of an inappropriate acoustic temporal bone window

# Study design

## Design

**Study type:** Observational non invasive

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|---|---|
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |

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| Primary purpose: | Diagnostic |

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 19-01-2015 |
| Enrollment: | 20 |
| Type: | Actual |

## Ethics review

Approved WMO

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|---|---|
| Date: | 06-08-2014 |
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |

## 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 |
|---|---|
| CCMO | NL49484.018.14 |