# Additional value of 3D rotational angiography in the detection of intracranial aneurysms.

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Prospectively compare the sensitivity of 2D DSA and 3D rotational angiography in the detection of intracranial aneurysms.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Aneurysms and artery dissections
Study type	Observational invasive

## Summary

## ID

NL-OMON32281

**Source** ToetsingOnline

**Brief title** Additional value of 3D angiography in the detection of aneurysms.

## Condition

• Aneurysms and artery dissections

**Synonym** balloon-like bulge of a blood vessel

**Research involving** Human

## **Sponsors and support**

**Primary sponsor:** Sint Elisabeth Ziekenhuis **Source(s) of monetary or material Support:** Nauwelijks extra kosten (beetje meer contrast);iets meer tijd

## Intervention

Keyword: 3D, Aneurysms, Angiography, Intracranial

### **Outcome measures**

#### **Primary outcome**

Comparing the number of detectable aneurysms on 2D DSA and 3D rotational

angiography.

#### Secondary outcome

NVT

# **Study description**

#### **Background summary**

Recently, we performed a retrospective study comparing sensitivity of 2D versus 3D rotational angiography in the detection of intracranial aneurysms. This study showed that approximately 20% of aneurysms were missed on 2D images alone. The aim is to design a prospective study comparing these imaging modalities in the detection of intracranial aneurysms.

#### **Study objective**

Prospectively compare the sensitivity of 2D DSA and 3D rotational angiography in the detection of intracranial aneurysms.

#### Study design

Location: Elisabeth ziekenhuis Tilburg

Name of the study: Additional value of 3D rotational angiography in the detection of intracranial aneurysms. Duration: from 1/10/2008 to 1/10/2009 Including 100 patients. Reading of the 2D and 3D images independently by two independent radiologists.

Standard imaging protocol: selective angiography of left internal carotid artery, right internal carotid artery en left vertebral artery. In case the right posterior inferior

cerebellar artery is not visible also a selective angiogram of the right vertebral artery is performed.

Additional 3D rotational angiography in case of suspected aneurysm on 2D DSA or on basis of SAH distribution on CT.

Angiographic imaging in research setting:

Same as standard imaging protocol supplemented with standard 3D rotational angiography of both internal carotid arteries as well as one vertebral artery.

#### Study burden and risks

The total length of the total study increases by 10 minutes. There will be about 0,4 mSv extra radiation dose and approx. 30 ml extra contrast given to the patient. The extra radiation dose as well as the extra contrast dose are very low and will not form a health risk for the patient.

# 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**

patients with a suspected intracranial aneurysm

## **Exclusion criteria**

Age < 18 years

# Study design

## Design

Study type: Observational invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Diagnostic	

## Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2008
Enrollment:	100
Туре:	Actual

# **Ethics review**

Approved WMO	
Date:	13-10-2008
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

# **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** CCMO ID NL21972.008.08