# Changes in aortic dimensions and pulsatility following endovascular aneurysm repair using the Nellix endoprosthesis.

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to quantitatively characterize the stresses and forces on an implanted endograft during the cardiac cycle in terms of longitudinal movement.

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

# Summary

### ID

NL-OMON41853

**Source** ToetsingOnline

Brief title Dynamic CTA after endovascular aneurysm repair

### Condition

• Aneurysms and artery dissections

**Synonym** aorta aneurysm, enlarged artery of the aorta

**Research involving** Human

### **Sponsors and support**

Primary sponsor: Rijnstate Ziekenhuis Source(s) of monetary or material Support: Stichting St Elizabeth, Stichting St. Elizabeth

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#### Intervention

Keyword: Dynamic CTA scan, Endovascular aneurysm repair, Nellix endoprosthesis

#### **Outcome measures**

#### **Primary outcome**

endograft displacement during the cardiac cycle (mm)

#### Secondary outcome

changes in normal aortic pulsatility following endograft placement (mm).

# **Study description**

#### **Background summary**

Abdominal aortic aneurysm (AAA) is a prevalent disorder affecting 4.3 to 8.8% of men over the age of 60.1 Since the introduction of endovascular aneurysm repair (EVAR) in the early 1990\*s, EVAR is performed in the majority of patients to prevent rupture. Endovascular Aortic replacement (EVAR) for the treatment of aortic aneurysms is an established endovascular technique. In spite of rigorous follow-up and improved stengraft desingn EVAR is still associated with procedure related complications like type I and II endoleak. To reduce the incidence of complications endograft development is ongoing. One of the latest developments is the Nellix endoprosthesis. Unlike current devices the Nellix endoprosthesis is composed of a stent-frame surrounded by endobags. During placement these endobags are filled with a polymer. This polymer fills up the original aneurysm sac, excluding the aneurysm and securing the stent-frame within the aorta. Although promising the stresses and forces exerted onto the endograft by aortic pulsatility may have an effect on the durability and functioning of the endograft. By evaluating endograft movement during the cardiac cycle (dynamic CTA) it is possible to assess the stress and force exerted onto the Nellix device. This might help gain insight into mechanisms underlying potential endograft failure, and aid the development of future devices with long-term durability.

#### **Study objective**

to quantitatively characterize the stresses and forces on an implanted endograft during the cardiac cycle in terms of longitudinal movement.

#### Study design

Observational case series (pilot)

#### Study burden and risks

Regular preoperative and follow-up imaging for EVAR planning and follow-up using the Nellix endoprosthesis consists of Computed Tomography Angiography preoperative and at six weeks, six months and one year after EVAR. In this study the preoperative and first follow-up CTA (6 weeks after EVAR) will be replaced by a Dynamic CTA.

### Contacts

**Public** Rijnstate Ziekenhuis

Wagnerlaan 55 Arnhem 6815 AD NL **Scientific** Rijnstate Ziekenhuis

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## **Trial sites**

#### **Listed location countries**

Netherlands

# **Eligibility criteria**

#### Age

Adults (18-64 years) Elderly (65 years and older)

### **Inclusion criteria**

scheduled endovascular (15 patients) aneurysm repair using the Nellix endoprosthesis. Informed consent

### **Exclusion criteria**

No specific contra-indications

# Study design

### Design

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

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	15-04-2015
Enrollment:	15
Туре:	Actual

# **Ethics review**

Approved WMO	
Date:	10-12-2014
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	05-03-2015
Application type:	Amendment

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# **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
ССМО	NL51011.091.14

### **Study results**

Date completed:	27-06-2018
Actual enrolment:	10