# Anatomic dynamics of the internal iliac artery after placement of iliac branched devices using ECG-gated Computer Tomography Angiography imaging (CTA) (IBD-dynamics)

Published: 05-10-2016
Last updated: 15-04-2024

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

## Summary

### ID

NL-OMON47337

**Source**
ToetsingOnline

**Brief title**
IBD-dynamics

### Condition

- Aneurysms and artery dissections

**Synonym**
Aneurysma

**Research involving**
Human

## Sponsors and support

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

## Intervention

**Keyword:** Dynamic CT, endovascular treatment, Iliac aneurysm, Iliac branced device

## Outcome measures

### Primary outcome

1. To compare the mobility of the hypogastic artery during the cardiac cycle

before and after implantation of the Gore IBE device (Sub-study A).

2. To quantitatively characterize the displacement during the cardiac cycle on

an implanted iliac branched endograft in conjunction with a non-dedicated n

balloon expandable IIA component (Cook IBD with Advanta V12 or Fluency) with

those in conjunction with a dedicated self expandable Internal Iliac cComponent

(Gore IBE device). (Sub-study B).

### Secondary outcome

Endpoints of the study will be;

a. Displacement and angulation of the IIA component during the cardiac cycle

compared to the native outflow vessel (Sub-study A)

b. Displacement and angulation of the IIA component during the cardiac cycle

compared to the main Gore IBE device/Cook IBD (Sub-study B)

c. Tortuosity of the IIA component, defined as the difference between the

highest angles of the central luminal line of the IIA component during the

various phases.

# Study description

### Background summary

The incidence of isolated common iliac artery (CIA) aneurysms is low, but in combination with an abdominal aortic aneurysm (AAA) they are found in approximately 20-40% of cases. Basically, two different endovascular strategies can be applied to treat a CIA aneurysm with, including 1. the coverage and 2. the preservation of blood flow to the internal iliac artery (IIA). Coil and coverage of the IIA is related to ischemic complications, including buttock claudication, erectile dysfunction and the more severe spinal and colonic ischemia. Iliac branched devices (IBD) have been developed to exclude CIA aneurysms preserving the IIA and currently three alternatives are on the market. Clinical results of these devices are promising but loss of patency is not uncommon. The major difference between the two devices is the IIA component. The Cook IBD uses a -non-dedicated IIA component, while in the GORE® EXCLUDER® Iliac Branch Endoprosthesis (Gore IBE device) a dedicated self expanding stent is used. Stresses and forces exerted onto the endograft by aortic pulsatility may have an effect on the durability and functioning of the endograft. Intermittent hinchpoints could also have an effect on stent integrity and stenosis. By evaluating endograft movement during the cardiac cycle (ECG-gated CTA) it is possible to assess the stress and force exerted onto the endograft. This might help gain insight into mechanisms underlying potential endograft failure, and aid procedural planning and the development of future devices with long-term durability.

### Study objective

This study has two objectives:
1. To compare the mobility of the hypogastic artery during the cardiac cycle before and six weeks after implantation of the Gore IBE device in conjunction with its dedicated self expandable Internal Iliac component (Sub-study A); 2. To quantitatively characterize the displacement of stents with regard to the main body and native IIA during the cardiac cycle on an implanted iliac branched endograft in conjunction with a non-dedicated IIA component (Cook IBD with Advanta V12 or Fluency) with those in conjunction with a dedicated self expandable Internal Iliac component (Gore IBE device). (Sub-study B)
Both substudies will gain insight into mechanisms underlying potential endograft failure, and aid procedural planning and the development of future devices with long-term durability.

### Study design

This study is designed as a multicenter prospective observational case series.
1. We will prospectively enroll 15 patients that are scheduled for endovascular

aneurysm repair using the Gore IBE device in conjunction with its dedicated self expanding Internal Iliac component.
2. We will compare 15 patients that have been treated in the period October 2006- July 2016 with the Cook IBD with a non-dedicated IIA component (Advanta-V12 or Fluency) and 15 matched patients treated with Gore IBE device.

### Intervention

Routine care consists of a preoperative and several postoperative CTA scans (at six weeks and one year following Gore IBE implantation). In A. The preoperative and first postoperative CTA will be replaced by ECG-gated CTA imaging and in B.

### Study burden and risks

More recordings will be made with a dynamic CTA in stead of a regular CTA. This wil lead to a very small increase of the radiation exposure because of the high speed of the dynamic CTA. Therefore, the unfavourable risks (radiation exposure) is very small. Results of this study will give insight into which treatment is the best for hte patients.

## 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

• Sub-study A. scheduled endovascular aneurysm repair using the Gore IBE device.
• Sub-study B. Patients that have been treated with an iliac branched device in the past (Oct 2006-May 2018) in conjunction with either a dedicated IIA component (Gore IBE device) or non-dedicated IIA component (Cook IBD) and who are scheduled for follow-up imaging within the period July 2016-December 2018.

## Exclusion criteria

No specific exclusion criteria. Patients will be treated according to the hospital*s standard practice.

# Study design

## Design

**Study type:** Observational non invasive

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

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 22-02-2017 |
| Enrollment: | 45 |
| Type: | Actual |

## Ethics review

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| Approved WMO Date: | 05-10-2016 |
| Application type: | First submission |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO Date: | 22-01-2019 |
| Application type: | Amendment |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO Date: | 28-01-2019 |
| Application type: | Amendment |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO Date: | 28-11-2019 |
| Application type: | Amendment |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |

## 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 | NL57938.091.16 |

# Study results

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|---|---|
| Date completed: | 11-12-2020 |
| Actual enrolment: | 49 |