# Flow augmentation study

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Coagulopathies and bleeding diatheses (excl thrombocytopenic) |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON55885

**Source**
ToetsingOnline

**Brief title**
Geko study

### Condition

- Coagulopathies and bleeding diatheses (excl thrombocytopenic)
- Embolism and thrombosis

**Synonym**
blod flow, post trombotic syndrome

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Vaatchirurgie
**Source(s) of monetary or material Support:** firstkind medical,industrie gesponsord

### Intervention

**Keyword:** flow, Geko device, venous stents

## Outcome measures

### Primary outcome

The main endpoint and parameter of this study is time-averaged maximum flow velocity (TAMFV), measured by duplex ultrasonography (DUS) using its pulse wave Doppler function

### Secondary outcome

Sex, age and body mass index will be obtained for demographic purposes. VAS score will be collected to evaluate the tolerability of the devices. Villalta score, Venous Clinical Severity Score, extent of post-thrombotic disease based on DUS and magnetic resonance venography, history of previous venous interventions, and CEAP score, will also be collected.

# Study description

### Background summary

Annually about 1 per 1000 people in Western European countries develop deep venous thrombosis (DVT). In about 25% of cases the caval, iliac and common femoral veins are affected. After a DVT the body will break down the cloth in order to recanalize the affected veins, however, in 70% of cases where the aforementioned vein segments are involved, inadequate recanalization occurs. This can vary from minor post-thrombotic changes to a remaining full occlusion of the vessel. If inadequate recanalization occurs, patients can develop debilitating symptoms with significant loss of quality of life, comparable to Chronic Obstructive Pulmonary Disease and heart failure.
In these types of patients, stenting can be performed with good clinical results and significant improvement in clinical scoring systems and quality of life. The first day after this intervention, patients receive intermittent pneumatic compression stockings (IPCS) to prevent early stent occlusion due to immobilisation.
Although stenting has been found to be an effective treatment, treatment becomes more difficult when post-thrombotic changes reach below the femoral confluence. An endophlebectomy has to be performed, where the common femoral vein is opened and post-thrombotic scarring tissue is surgically removed.

However, post-thrombotic tissue is still present in the femoral and deep femoral vein, for which we have no adequate treatment options at the moment. Following this procedure, a temporary arteriovenous fistula (AVF) is created to ensure proper inflow in the operated and stented tract to prevent reocclusion. Despite these measures and adequate post-operative anticoagulation, occlusion or stenosis of the affected tract still occurs in the early phases post-operatively due to thrombogenic circumstances, leading to additional interventions.
Since the geko can augment venous flow, we woner whether the IPCS, which we now use during the first two days after intervention and the Geko can stimulate flow in the same way. This system is easy to use and can be worn while walking. Therefore, we would like to investigate if the geko augments venous flow in post-thrombotic limbs and compare it to the IPCS we use now, which has never been performed in this patient group 1.

In patients with a hybride procedure we will investigate whether the Geko (with occluded AVF) will augment flow like an open fistula.
Additionally, a better patient selection with identification of patients who will not benefit from treatment will likely also lead to fewer complications. The Treadmill Pilot Study (NL44588), which has been completed in our centre, already showed us that venous pressure is significantly higher in diseased limbs, compared with the contralateral healthy limbs, during walking, standing, and in the supine position. Follow-up has to tell us though whether pressure can be predictive of complications. Pressure in supine position can be easily measured during intervention, though differences in the supine position are relatively small with a lot of overlap. A follow-up to the Treadmill Pilot Study should therefore include supine pressure measurements with provoked flow. Higher flow means larger variation in pressure and might therefore lead to a practical parameter that identifies patients at risk for occlusion.

Knowing what device to use to provoke flow in such a study will be an additional benefit of testing whether IPCS and geko augments flow.

In conclusion, to improve post-operative care, diminish reocclusion, and further our research in finding a parameter useful for better patient treatment selection, this study is necessary to investigate whether geko can augment flow in post-thrombotic limbs.

## Study objective

Primary Objective: The primary objective of this study is to identify whether the Geko system can augment flow compared to IPCS in post-thrombotic limbs before after stenting.(group 1) In group 2 we want to identify whether the Geko with occluded fistula stimulates blood flow in the same degree as the hybrid treated patients. (group 2)

### Study design

This is a cross-sectional interventional study in patients with a post-thrombotic obstruction undergoing a percutaneous procedure (PTA, stenting). Flow will always be measured in the external iliac vein, 2 cm above the level of Poupart*s ligament. Patients will be tested before the percutaenous procedure, 1-2 weeks after the *ntervent*on and 6 week after discharge. The order of device use (IPCS an Geko device) will be randommized. If a patient randomises for Geko, the Geko device and the standard treatment with IPCSs will be compared. I(n group 2 we will compare GEKo with occluded fistula with open fistula.

The measurements will start in supine position after a five minutes* rest. The Geko device will be activated and after five minutes the flow will be measured for a period of 5 minutes. Following this first measurement there will be another resting of 5 minutes. Then the IPCSs/ fistula will be activated and flow will be measured for 5 minutes following the 5 minutes of device activation.
The Geko device will be activated at a frequency of 1 Hz (this is standard for device).

### Intervention

Geko device versus IPCS or open fistula

### Study burden and risks

The burden of this study is relatively low as both geko and IPCS are non-invasive, will be administered for a very short period of time and patients do not need to visit the hospital. The geko device can cause some mild discomfort or irritation of the skin though.

## Contacts

**Public**
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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

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

## Inclusion criteria

Only patients that fulfill either a) or b) and c) are able to participate into this study:
a) Patients that suffer from post-thrombotic obstruction, which are in need of a percutaneous intervention by stenting (will be considered as study percutaneous group 1).
b) Patients that suffer from post-thrombotic obstruction whereby endophlebectomy and placement of an AVF has to be performed (will be considered as study hybrid group 2).
c) Patients have to be minimally 18 years of age or older.

## Exclusion criteria

Peripheral arterial disease,
comorbidities leading to impaired muscle function of either lower limb,
co-morbidities affecting the circulatory system,
history of deep venous surgery in either lower limb or groin,
allergies to the plasters,
pregnancy.

# Study design

## Design

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|---|---|
| Study type: | Interventional |
| Intervention model: | Crossover |
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Prevention |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 03-04-2017 |
| Enrollment: | 51 |
| Type: | Actual |

## Medical products/devices used

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|---|---|
| Generic name: | Geko device |
| Registration: | Yes - CE intended use |

# Ethics review

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|---|---|
| Approved WMO Date: | 15-02-2017 |
| Application type: | First submission |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |
| Approved WMO Date: | 29-12-2017 |
| Application type: | Amendment |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |
| Approved WMO Date: | 30-09-2021 |
| Application type: | Amendment |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |

# 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 | NL59864.068.16 |