# Translesional pressure measurements to assess clinical relevance of a mesenteric artery stenosis

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Intra-arterial pressure measurements are currently the most promising tool to guide clinical decision making in patients with suspected CMI. Implementation of pressure measurements could result in major improvements in quality of life by tailoring...

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| **Ethical review** | Approved WMO |
| **Status** | Pending |
| **Health condition type** | Gastrointestinal vascular conditions |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON57447

**Source**
ToetsingOnline

**Brief title**
Pressure

### Condition

- Gastrointestinal vascular conditions

**Synonym**
Chronic mesenteric ischemia, intestinal angina

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Erasmus MC, Universitair Medisch Centrum Rotterdam
**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Chronic mesenteric ischemia, Intra-arterial pressure measurements, Mesenteric artery stenting

## Outcome measures

### Primary outcome

-To assess the predictive performance of the Pd/Pa ratio after administration

of a vasodilator to predict the clinical success of mesenteric artery stenting.

### Secondary outcome

- To assess the improvement in quality of life after a successful endovascular

mesenteric artery revascularization procedure

- To compare the improvement in quality of life between patients with pressure

measurements indicating clinical success of revascularization and patients with

pressure measurements indicating no clinical success of revascularization

- To assess the cost-effectiveness of future implementation of intra-arterial

pressure measurements prior to a mesenteric artery revascularization

- To assess the predictive performance of pressure measurements to predict

clinical success of mesenteric artery stenting in patients with stenosis

of a single mesenteric artery.

- To assess the predictive performance of pressure measurements to predict

clinical success of mesenteric artery stenting in patients with stenosis

of >=2 mesenteric arteries.

- To assess the predictive performance of pressure measurements to predict

clinical success of mesenteric artery stenting in patients with a stenosis of

50-70%.

- To assess the predictive performance of pressure measurements to predict clinical success of mesenteric artery stenting in patients with an in-stent stenosis.

- To determine the correlation of pressure measurements with the severity of stenosis.

- To determine the duration of pressure measurements.

- Register complications within 30 days after mesenteric artery pressure measurements.

- To compute the pressure drop using computational models

- To compare the computed to the measured pressure drop

# Study description

**Background summary**

Chronic mesenteric ischemia (CMI) is an incapacitating disease with a vast impact on quality of life due to severe abdominal pain after a meal, resulting in fear of eating and subsequent severe weight loss(1-3). CMI has an incidence of 9.2 per 100,000, which increases with age to up to 44.3 per 100,000 in persons of >=80 years. These incidence rates are higher than the incidence rates of other more well-known disease, such as esophageal cancer (4.3 per 100,000) or ruptured abdominal aortic aneurysms (7.0 per 100,000) and even approximates the incidence of Crohn*s disease (10.9 per 100,000). The prevalence of atherosclerotic mesenteric artery stenosis, the leading cause of CMI, is even higher (6-29%). An extensive collateral circulation protects the gut against ischemia in the majority of patients. Hence, not all mesenteric artery stenoses result in CMI and only those stenoses that are hemodynamically significant should be treated. In recent years the DMIS (The Dutch Mesenteric Ischemia Study group) has been searching for a reliable tool to assess hemodynamic significance of a mesenteric artery stenosis, while accounting for the collateral circulation, in order to guide treatment decisions and avoid clinically unbeneficial revascularization procedures.

**Study objective**

Intra-arterial pressure measurements are currently the most promising tool to guide clinical decision making in patients with suspected CMI. Implementation of pressure measurements could result in major improvements in quality of life by tailoring treatment to the patient*s needs, thereby, improving the clinical success of mesenteric artery revascularization and decreasing complication risks. This will ultimately result in a reduction of population based healthcare costs by facilitating allocation of health care resources to those patients actually benefitting from treatment. The DMIS has designed a multicenter study to determine the ability of intra-arterial pressure measurements using a microcatheter to predict clinical success of mesenteric artery revascularization, to set an optimal cut-off for the guidance of treatment decisions, and to determine cost-effectiveness of future clinical implementation of intra-arterial pressure measurements.

### Study design

This study is a prospective multicentre cohort study. All patients undergoing an interventional endovascular procedure of the mesenteric arteries are asked to participate. At the intake at the outpatient clinic before the endovascular procedure patients will receive a Patient Information Folder, explaining the details of the study. Patients will have the opportunity to ask questions about the study before informed consent is signed.

### Study burden and risks

The potential risks of this study are deemed low. The difference with patients not participating in this study is performance of translesional pressure measurements. Measurements are performed using the same sheath and guiding catheter as used during the mesenteric artery intervention. A microcatheter is advanced over a guidewire distal to the stenotic lesion to perform these pressure measurements. Using of microcatheters to pass stenotic lesions is common practice in mesenteric artery angioplasty and stenting procedures, therefore no additional complications are expected due to the pressure measurements. After performing the pressure measurements, the angioplasty and stent placement is performed. In the rare occasion of a dissection, consecutive stenting can be performed to treat the dissection (if not performed already for treatment purposes).

## Contacts

**Public**
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr. Molewaterplein 40

Rotterdam 3015 GD
NL
**Scientific**
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr. Molewaterplein 40
Rotterdam 3015 GD
NL

# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)

## Inclusion criteria

1. All patients with CMI undergoing an endovascular procedure of the mesenteric arteries
2. Age >=18 years of age
3. Patients who gave informed consent

## Exclusion criteria

1. Patients presenting with acute mesenteric ischemia
2. Common origin of the SMA and CA (normal variant)
3. Patients unable to give informed consent
4. Pregnancy
5. Other criteria the physician considers not compatible with this study

# Study design

## Design

**Study type:** Observational invasive

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

## Recruitment

NL

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|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 17-02-2025 |
| Enrollment: | 125 |
| Type: | Anticipated |

# Ethics review

Approved WMO

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| Date: | 19-02-2025 |
| Application type: | First submission |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |

# 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 | NL87259.078.24 |