CFD-MAS

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This study aims to develop a RI using CTA-based CFD simulations for estimating the hemodynamic significance across mesenteric arterial stenoses (MAS).

Ethical review	Not available
Status	Pending
Health condition type	Arteriosclerosis, stenosis, vascular insufficiency and necrosis
Study type	Observational non invasive

Summary

ID

NL-OMON57474

Source
Onderzoeksportaal

Brief title
CTA-based Computational Fluid Dynamic Simulations For Estimating Hemodynamic Significance Across Mesenteric Arterial Stenoses

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis
- Gastrointestinal stenosis and obstruction

Synonym
Chronic mesenteric ischaemia

Research involving
Human

Sponsors and support

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

Intervention

- Other intervention

Explanation

N.a.

Outcome measures

Primary outcome

To develop RI by CTA-based CFD simulations for estimating hemodynamic significance across MAS.

Secondary outcome

To compare the sensitivity and specificity of RI in predicting definitive diagnosis of CMI to traditional parameters, such as pre-revascularization doppler ultrasound, CTA geometry information (stenosis degree), and intra-arterial pressure measurements.

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 weight loss. CMI is most frequently caused by an atherosclerotic mesenteric artery stenosis, which is a frequent finding in the general population (6-29%). However, a mesenteric artery stenosis (MAS) is often asymptomatic. CMI is less prevalent then the prevalence of a MAS probably due to an extensive collateral circulation protecting the gut against ischemia. Especially in patients with multivessel disease revascularization treatment is recommended. Yet, substantial treatment failure (27-31% in patients with single vessel disease) is still a problem, probably since not every significant stenosis on CT leads to a hemodynamic significance due to the collateral network. In this study, this hypothesis will be tested by using computational fluid dynamics (CFD) simulations based on the Navier-Stokes equation to assess the hemodynamic significance of MAS, regardless of outflow conditions, by developing a novel resistance index (RI) in a previous retrospective study where the pressure drop over a stenosis was measured. The computational pressure measurements will be compared to the measured intra-arterial pressure measurements.

Study objective

This study aims to develop a RI using CTA-based CFD simulations for estimating the hemodynamic significance across mesenteric arterial stenoses (MAS).

Study design

Patients who were included in a previous already published study (MEC-2018-1265) are eligible in this study. In this retrospective study patients were included who underwent a digital subtraction angiography (DSA) with intended revascularization of a stenotic mesenteric artery because with a consensus diagnosis of chronic mesenteric ischemia (CMI). During this revascularization intra-arterial pressure measurements before and after intra-arterial administration of nitroglycerin had been obtained. Between April 2015 and May 2017, a total of 37 patients were included and 41 intra-arterial pressure measurements were done. This study is published in the Journal of Vascular and Interventional Radiology in March 2020.

Intervention

Not applicable

Study burden and risks

This study poses no burden to the patients as it consists solely of respective review of their (electronic) patient records and CTA images.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Patients who were included in the previous study (MEC-2018-1265)

Exclusion criteria

CTA slice thickness ≥ 5 mm

Study design

Design

Study phase:	N/A
Study type:	Observational non invasive
Intervention model:	Single
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Aetiology

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2025
Enrollment:	37
Type:	Anticipated

Medical products/devices used

Product type:	N.a.

IPD sharing statement

Plan to share IPD: No

Plan description
N.a.

Ethics review

Not available
Date:	06-02-2025
Application type:	First submission
Review commission:	Validatie nWMO registratie door CCMO

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
Research portal	NL-009233