Microvascular Resistance Reserve And Myocardial Mass
A Prospective exploratory study

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The primary objective of this study is to compare MRR measured at two locations in the LAD (proximal LAD and mid-LAD, i.e. distal to the first large diagonal branch) and to investigate if MRR remains unchanged with this change of myocardial mass.

Ethical review	Approved WMO
Status	Pending
Health condition type	Myocardial disorders
Study type	Observational invasive

Summary

ID

NL-OMON57091

Source
ToetsingOnline

Brief title
MRR Mass study

Condition

- Myocardial disorders

Synonym
ANOCA (Angina non obstructive coronary arteries)

Research involving
Human

Sponsors and support

Primary sponsor: cardiologie
Source(s) of monetary or material Support: er is geen financiering er is geen extra geld/materiaal nodig

Intervention

Keyword: Angina non obstructive coronary arteries, coronary physiology, Microvascular disease, microvascular resistance reserve

Outcome measures

Primary outcome

The primary objective of this study is to compare MRR measured at two locations

in the LAD (proximal LAD and mid-LAD, i.e. distal to the first large diagonal

branch) and to investigate if MRR remains unchanged with this change of

myocardial mass.

Secondary outcome

na

Study description

Background summary

Coronary microvascular dysfunction (CMD) is increasingly recognized as a common cause of chest pain and is associated with impaired quality of life and poor clinical outcome. This diagnosis can be considered when patients have chest pain with normal coronary arteries (ANOCA; angina non obstructive coronary arteries).
Until recently, precise techniques to evaluate and quantify CMD were not available.
For decades, only substitutes of flow and resistance were used such as Doppler-CFR and bolus thermodilution-based IMR, which are either crude, non-specific, difficult to obtain in a considerable number of patients, and operator-dependent.
Since 2016, direct flow and resistance measurement in the coronary circulation has become feasible for clinical use in the catheterization laboratory, using continuous intracoronary thermodilution with low infusion rates of saline.
This method directly quantifies absolute coronary blood flow (Q) and microvascular resistance (Rμ) at rest and at hyperemia, providing an accurate, reproducible and quantitative evaluation of the coronary microcirculation. This is now part of the standard care in the catheterization lab when investigating the microcirculation in patients with ANOCA.

From the Continuous thermodilution measurements enable also calculation of Microvascular Resistance Reserve (MRR) can be directly performed. The index MRR, introduced in 2021, is simply calculated from the flow and pressure measurements and is a specific measure of the coronary microcirculation, independent of any kind of hidden or overt epicardial disease. In addition, MRR has the theoretical advantage of being independent of the myocardial mass (perfusion territory) supplied by the respective coronary artery. However, direct proof of this latter characteristic in humans, has not been obtained so far.
The aim of this present exploratory study, is to obtain such direct proof by measuring MRR not only in the proximal LAD artery, but also in the mid-LAD, just distal to a large diagonal branch and showing that both values are (almost) equal.

Study objective

The primary objective of this study is to compare MRR measured at two locations in the LAD (proximal LAD and mid-LAD, i.e. distal to the first large diagonal branch) and to investigate if MRR remains unchanged with this change of myocardial mass.

Study design

A prospective, exploratory study comparing MRR in 30 patients at two locations in the LAD artery:
Proximal LAD (regular measurement) and mid-LAD (study measurement).

Study burden and risks

none

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

In order to be eligible to participate in this study a subject must meet all of the following criteria:
• Patient must be accepted/planned for regular coronary function testing based on the decision of the cardiologist. Usually, these will be patients with typical angina but (almost) normal coronary arteries
• Age >= 18 years

Exclusion criteria

• Extremely tortuous LAD vessel
• Proximal LAD diameter less than 2.5 mm
• Pregnancy
• Unable to provide consent

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2024
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO

Date:	04-11-2024
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL87694.100.24