European microCirculatory Resistance and Absolute Flow Team-The Euro-CRAFT Registry
Prospective evaluation of the impact of coronary themodilution on clinical outcomes in chronic coronary syndromes

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To assess the rate of major adverse cardiac and cerebrovascular events (MACCE) between patients with and without coronary microvascular disease (CMD) based on Microvascular Resistance Reserve (MRR) at 1 year follow-up.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Coronary artery disorders
Study type	Observational invasive

Summary

ID

NL-OMON56717

Source
ToetsingOnline

Brief title
Euro-CRAFT registry

Condition

- Coronary artery disorders

Synonym
chronic coronary syndromes, disease of the small coronaries

Research involving

Human

Sponsors and support

Primary sponsor: CoreAalst BV
Source(s) of monetary or material Support: Grant van Hexacath,Hexacath

Intervention

Keyword: Coronary Arteries, microvascular, resistance measurement

Outcome measures

Primary outcome

Primary endpoint will be the rate of major adverse cardiac and cerebrovascular events at one year (MACCE - defined as cardiovascular death, myocardial infarction, revascularization, angina and heart failure-related hospitalizations, and stroke) between patients with and without CMD based on MRR at 1 year follow-up.

Secondary outcome

Main Secondary endpoints:

1. Relationship between MACCE*s and each thermodilution derived metrics of microvascular function (i.e., absolute hyperemic flow, absolute hyperemic resistance, IMR and CFR).

2. Relationship between the presence and severity of angina, assessed by SAQ-19, and each individual thermodilution-derived metrics of microvascular function (i.e., absolute hyperemic flow, absolute hyperemic resistance, IMR and CFR).

3. Relationship between the presence and severity of angina, assessed by the Euro-CRAFT app, and each individual thermodilution-derived metrics of

microvascular function (i.e., absolute hyperemic flow, absolute hyperemic resistance, IMR and CFR).

4. Safety of continuous and bolus thermodilution measurements, as assessed by adverse event registration.

5. To determine cut-off values of thermodilution-derived indices.

6. To assess the prevalence of CMD based on MRR in patients with angina and non-obstructive coronary artery disease (NOCAD).

Study description

Background summary

The arterial coronary circulation can be subdivided into two compartments: the epicardial arteries and the microcirculation.

The microcirculation consists of arteries smaller than 500 micrometers and by the capillary network. Its main function is to match blood flow to the needs of the cardiac contractile apparatus. Accordingly, the function of the microvasculature is primarily characterized by the microvascular resistance, an index that is difficult to assess.

In a sizable proportion of patients with chest pain, no significant epicardial narrowing can be seen at coronary angiography, even in case of typical anginal complaints. This condition is defined as ischemia with no obstructive coronary arteries (INOCA)(3-6) and often related to microcirculatory dysfunction. In addition, in patients with acute coronary syndromes, normal or near normal coronary angiograms may be found. Such condition is known as myocardial infarction with no obstructive coronary arteries (MINOCA).

We have introduced and validated a new invasive method to measure absolute coronary flow (in mL/min) and absolute microvascular resistance (in Woods Units, WU). The method is based on the continuous thermodilution principle. Saline at room temperature is slowly but steadily infused in the proximal part of the artery. The accuracy of thermodilution-derived flow measurements has been validated against 15H2O-PET flow measurements.

A necessary prerequisite for clinical application of absolute coronary flow

(Q), microvascular resistance (Rμ) and of MRR is to establish some basic characteristics of this new indices, to investigate feasibility and safety when obtained on a broader scale by continuous thermodilution, to compare its value to other existing metrics, and to correlate MRR to clinical outcome data.

Study objective

To assess the rate of major adverse cardiac and cerebrovascular events (MACCE) between patients with and without coronary microvascular disease (CMD) based on Microvascular Resistance Reserve (MRR) at 1 year follow-up.

Study design

The Euro-CRAFT Registry is an investigator-initiated, prospective, multicentric, international registry of patients undergoing functional assessment of the coronary microcirculation using the continuous thermodilution technique.
Angina and quality of life questionnaires (Seattle Angina Questionnaire 19 - SAQ19, Euro-CRAFT smartphone app) will be obtained at baseline, at 6 months, and 1-year follow-up.
Clinical follow-up will be performed at 1 year (optionally until 5 years).

Study burden and risks

In-hospital follow-up during baseline test: The occurrence of any complication or adverse events should be reported. Hospital discharge will be done following local practices.

Subsequent clinical follow-up will take place after 1 year and, optional yearly till 5 years. SAQ-19 will be assessed at baseline, 6 months and 1 year follow-up. Clinical follow-up and collection of questionnaires can be performed either by in-hospital
visit or by phone.

Anticipated benefits for the patient
This prospective study doesn*t interfere with the normal diagnostic and therapeutic process. The systematic assessment of the continuous thermodilution curves may lead to a definitive diagnosis and guide treatment strategy. There are no other anticipated benefits regarding the medical
treatment or treatment strategy before, during or after the study as there is no other interference with any of them. The definite treatment strategy will be based on currently applied strategies and guidelines and will not change due to the study. All treatment decision will be done at operator discretion.

Anticipated risks for the patient

No additional risks for the patients are expected. This study does not interfere with any common or generally used test or processes during the work-up of CAD in any patient. No additional imaging or acquisition protocols are mandatory. No additional radiation is warranted. The potential risk for the patient applies to the known and common risks during the diagnostic work-up process or during invasive coronary angiography (ICA) with assessment of coronary microcirculation but are unrelated to this study. Invasive functional assessment of the microcirculation has been recommended as class IIa in INOCA according to the ACC/AHA Chest Pain Guideline.

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

Consecutive patients in whom physiological assessment of the microcirculatory function including continuous coronary thermodilution has been performed with a Pressure-wire X within the context of routine clinical care.

Exclusion criteria

. Age <18 years
2. Unable to provide written informed consent (IC)
3. Unstable hemodynamics
4. Ongoing chest pain
5. Previous CABG
6. Moderate to severe valvular heart disease
7. Uncontrolled or recurrent ventricular tachycardia.
8. Active liver disease or hepatic dysfunction, defined as AST or ALT > 3 times the ULN.
9. Comorbidity with life expectancy <= 2 years.
10. Severe renal dysfunction, defined as an eGFR <30 mL/min/1.73 m2.
11. Subject is currently participating in another investigational drug or device clinical study.
12. Presence of other anatomic or comorbid conditions, or other medical, social, or psychological conditions that, in the investigator's opinion, could limit the subject's ability to participate in the clinical investigation or to comply with follow-up requirements, or impact the scientific soundness of the clinical investigation results.

Study design

Design

Study phase:	4
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-06-2024
Enrollment:	100
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	09-04-2024
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
Other	Clintrials.gov nummer volgt, staat nog niet openbaar.
CCMO	NL83896.100.23