Relationship between regulation of peripheral and intracoronary microvascular blood flow in patients with ischemia and no obstructive coronary arteries

Published: 22-12-2021
Last updated: 16-11-2024

The primary objective of the study is to test whether peripheral endothelial function assessed using Laser speckle contrast analysis and CED measured with ICFT are correlated.

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

Summary

ID

NL-OMON52365

Source
ToetsingOnline

Brief title
PERIPHERAL-FLOW

Condition

- Coronary artery disorders

Synonym
coronary microvascular dysfunction, Endothelial function

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Hartstichting

Intervention

Keyword: Endothelial function, INOCA, Microvascular blood flow, Peripheral microvascular function

Outcome measures

Primary outcome

The main study end point is the difference in peripheral endothelial function

between INOCA and HFpEF patients with and without CED measured with ICFT.

Secondary outcome

1) The relationship between microvascular reactivity measured using EndoPAT and

LASCA in patients with INOCA and HFpEF.

2) The difference in peripheral endothelial function measured with LASCA

between INOCA and HFpEF patients with and without an abnormal CFR and HMR

measured with ICFT

Study description

Background summary

Coronary endothelial dysfunction (CED) has been proposed to cause signs and symptoms of myocardial ischaemia in patients with angina but no obstructive coronary artery disease (CAD) and heart failure with preserved ejection fraction (HFpEF) and is associated with an increased risk of adverse cardiac events. Currently, CED can only be detected with invasive coronary function testing (ICFT).
However, it has been suggested that CED is a component of systemic endothelial dysfunction and is associated with endothelial dysfunction in other microvascular beds. The cutaneous microcirculation is suitable for microvascular function studies and has been shown to correlate with muscle

microvascular function. The recently developed Laser speckle contrast analysis (LASCA) technique enables non-invasive monitoring of microvascular blood flow in superficial microvascular beds. In combination with iontophoresis of acetylcholine, nitroprusside and insulin, LASCA allows evaluation of peripheral microvascular endothelial and smooth muscle function. While LASCA is an established technique, the association between CED diagnosed with ICFT and an abnormal peripheral endothelial function measured by LASCA is currently unknown.

Study objective

The primary objective of the study is to test whether peripheral endothelial function assessed using Laser speckle contrast analysis and CED measured with ICFT are correlated.

Study design

Observational cross-sectional cohort study.

Study burden and risks

Study participants do not benefit from participation in this study. The burden of this study is low. This study protocol consists of 1 additional clinical visit which will take about 2 hours. The total risks associated with participation are classified as being low, because the risks for adverse events and serious adverse events from a local and transient stimulus in skin are minimal. Iontophoresis of acetylcholine, nitroprusside and insulin does not cause any skin damage and the used dosages are very small and as such, the stimuli do not cause any systemic effects.

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

- Clinical indication for elective ICFT
- Persistent angina defined as symptoms of angina at least 2 times a month for the last 3 months
- Absence of obstructive CAD diagnosed by CCTA and/or CAG.
- Being able to speak and understand the Dutch or English language
- Signed informed consent

Exclusion criteria

- Under 18 years of age.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	03-01-2022
Enrollment:	109
Type:	Actual

Medical products/devices used

Generic name:	PeriCam PSI system and PeriIont micropharmacology system
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	22-12-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-03-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL79036.029.21

Study results

Date completed: 05-09-2024

Summary results
Trial ended prematurely