Inclusive invasive physiological assessment in angina syndromes - Angina with no obstructive coronary artery disease

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20739

Source
Nationaal Trial Register

Brief title
ILIAS ANOCA

Health condition

Angina syndromes and no obstructive coronary artery disease (ANOCA)

Sponsors and support

Primary sponsor: Academic Medical Research B.V.
Source(s) of monetary or material Support: Restricted Research Grant Philips IGDT

Intervention

Outcome measures

Primary outcome

To assess the effectiveness of a stepwise medical therapy approach guided by coronary

function testing in reducing angina burden of patients with angina pectoris and no obstructive epicardial coronary artery disease based on clinically indicated invasive coronary angiography, compared with the control of angina provided by standard clinical care not guided by coronary function testing

Secondary outcome

1. To identify the relevance of endothelial dysfunction in the spectrum of ANOCA endotypes
2. To evaluate the appropriateness of current criteria for abnormal vasoconstriction and abnormal vasodilatation to sensitively rule out significant abnormalities in coronary function.
3. To compare angiography-derived coronary flow reserve and microvascular resistance versus invasive coronary flow reserve and microvascular resistance.
4. To assess the cost-effectiveness of a stepwise medical therapy approach guided by coronary function testing compared with standard clinical care not guided by coronary function testing.
5. To assess the prognostic value of biomarkers (hs-troponin, NTproBNP, CRP). at baseline across the ANOCA-endotypes.
6. To assess sex differences across the various ANOCA-endotypes and the impact of sex differences on diagnosis, treatment, and health status.

Study description

Background summary

The primary objective of this study is to assess the effectiveness of a stepwise medical therapy approach guided by coronary function testing in reducing angina burden of patients with angina pectoris and no obstructive epicardial coronary artery disease based on clinically indicated invasive coronary angiography, compared with the control of angina provided by standard clinical care not guided by coronary function testing

Study objective

In patients with ANOCA, identification of specific endotypes of vascular dysfunction with intracoronary testing, followed by pharmacological and nonpharmacological interventions aligned to the identified endotype, leads to better control of angina and well-being compared to standard care not guided by intracoronary testing.

Study design

Primary endpoint:

Within-subject modification of SAQ-score at 6 months from baseline between the standard care and ICFT-guided arm.

Secondary endpoints:

1. Within-subject modification of SAQSS over time (6-, 12-month follow-up) between the standard care and ICFT-guided arm.
2. Within-subject modification of SAQSS (6-, 12-month follow-up) over time between the standard care and ICTF-guided arm for patients with
and without endothelial dysfunction.
3. Within-subject modification of SAQSS over time (6-, 12-month follow-up) between the standard care and ICFT-guided arm in patients with negative ICFT according to COVADIS criteria but replication of their usual angina during ICFT.
4. Within-subject modification of health status (EQ5D) over time (6-, 12- month follow-up) between the standard care and ICFT-guided study arms.
5. Within-subject modification of SAQSS over time (6-, 12-month follow-up) between the standard care and ICFT-guided study arms in female versus male patients.
6. Cost-effectiveness of an ICFT-guided treatment strategy versus standard care.
7. Difference in 12-month major adverse cardiac event rate (composite of hospitalization for angina, repeat coronary angiography, myocardial
infarction, and death) between the standard care and ICFT-guided arm.
8. Within-subject modification of SAQSS score at 24-month follow-up versus 12-month follow-up after unblinding and cross-over to ICFTguided
medical therapy of patients initially randomized to standard care.

Intervention

Intracoronary function testing guided therapy

Contacts

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Eligibility criteria

Inclusion criteria

- Age ≥ 18 years.
- Patient referred for elective coronary angiography, at the discretion of the treating physician, for suspected angina (and/or angina-equivalent) symptoms.
- Absence of obstructive coronary artery disease evident in a main coronary artery (diameter stenosis<50%, iFR>0.89, or FFR >0.80).

Exclusion criteria

-A noncoronary indication for invasive angiography, e.g., valve disease, hypertrophic obstructive cardiomyopathy
-A life expectancy of less than 2 years.
-Inability to sign an informed consent, due to any mental condition that renders the subject unable to understand the nature, scope, and possible consequences of the trial or due to mental retardation or language barrier.
-Potential for non-compliance towards the requirements for follow-up visits.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL
Recruitment status:	Pending
Start date (anticipated):	01-06-2021

Enrollment:	250
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	11-05-2021
Application type:	First submission

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
NTR-new	NL9474
Other	METC AMC : METC 2021_063

Study results