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

Gepubliceerd: 11-05-2021 Laatst bijgewerkt: 13-12-2022

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...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20739

Bron
NTR

Verkorte titel
ILIAS ANOCA

Aandoening

Angina syndromes and no obstructive coronary artery disease (ANOCA)

Ondersteuning

Primaire sponsor: Academic Medical Research B.V.
Overige ondersteuning: Restricted Research Grant Philips IGDT

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

Intracoronary function testing guided therapy

Contactpersonen

Publiek

Amsterdam UMC
Coen Boerhout

0634777615

Wetenschappelijk

Amsterdam UMC
Coen Boerhout

0634777615

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

-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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-06-2021
Aantal proefpersonen:	250
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	11-05-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9474
Ander register	METC AMC : METC 2021_063

Resultaten