

Multicenter Study on Coronary Anomalies in The Netherlands

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N.A.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON26172

Bron

NTR

Verkorte titel

MuSCAT

Aandoening

Anomalous coronary artery from the opposite sinus
Right or left coronary artery from the pulmonary artery
Coronary arteriovenous fistulas

Ondersteuning

Primaire sponsor: N.A.

Overige ondersteuning: N.A.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- (cardiac) death
- Myocardial ischemia attributable to the ACAOS

- Re-intervention after surgery
- Intervention after initially conservative treatment

Toelichting onderzoek

Achtergrond van het onderzoek

Evidence for the treatment of patients with coronary anomalies is scarce and treatment decisions are thus very heterogeneous, especially for patients with an anomalous coronary artery from the opposite sinus (ACAOS) with an interarterial course, that are potentially prone to sudden cardiac death. In this study, prospectively included patients with an ACAOS receive work-up according to a structured protocol using CT-angiography, ischemia detection testing, echocardiography and coronary angiography with intracoronary measurements to assess anatomical and physiological characteristics of the ACAOS. During follow-up, surgical and functional results are evaluated by CT-angiography, ischemia detection testing and a quality-of-life-questionnaire. Evaluated are (cardiac) death, myocardial ischemia attributable to the ACAOS, re-intervention after surgery and intervention after initially conservative treatment, and the influence of work-up examinations on treatment choice. Patients are followed-up for at least 2 years.

Registry is done for patients with right or left coronary artery from the pulmonary artery and coronary arteriovenous fistulas.

The aim is to provide evidence substantiated recommendations for diagnostic work-up, treatment and follow-up of patients with anomalous coronary arteries.

Doel van het onderzoek

N.A.

Onderzoeksopzet

September 2020 start enrollment

December 2023 end enrollment

2026 end of follow-up last included patient

Onderzoeksproduct en/of interventie

- Coronary CT angiography, using 0.5-1mm slices (work-up and follow-up after surgery)
- Transthoracic echocardiography (work-up)
- CAG with IVUS and FFR measurement (and iFR or CFR) of the interarterial and septal ACAOS using adrenalin and adenosine or dobutamin (work-up)
- Ischemia detection test (work-up and follow-up after surgery)

Every participating hospital will perform the tests according to the physicians insights and possibilities of the hospital. Preferably all examinations are done as standard of care, because each test examines a different physiological aspect.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients with the diagnosis of:

- ACAOS
- Coronary artery from the pulmonary artery
- Coronary arteriovenous fistula

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- History of (hemodynamically significant) congenital heart defects other than the coronary anomaly
- ACAOS patients with proven coronary atherosclerotic disease with significant stenosis (after treatment of the stenosis, patients with can be ACAOS are reconsidered for inclusion)

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	Niet-gerandomiseerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2020
Aantal proefpersonen:	210
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:	15-07-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 55795
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8777
CCMO	NL69310.058.19
OMON	NL-OMON55795

Resultaten

Samenvatting resultaten

Koppel CJ, Driesen BW, de Winter RJ, et al. The first multicentre study on coronary anomalies in the Netherlands: MuSCAT. Neth Heart J. 2021 Mar 8. doi: 10.1007/s12471-021-01556-9. Epub ahead of print. PMID: 33683666. <https://pubmed.ncbi.nlm.nih.gov/33683666/>