Multicenter Study on Coronary Anomalies in The Netherlands

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26172

Source
NTR

Brief title
MuSCAT

Health condition

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

Sponsors and support

Primary sponsor: N.A.
Source(s) of monetary or material Support: N.A.

Intervention

Outcome measures

Primary outcome

-(cardiac) death
-Myocardial ischemia attributable to the ACAOS
-Re-intervention after surgery

-Intervention after initially conservative treatment

Secondary outcome

-Quality of life based on the SF-36 questionnaire
-Thoracic complaints (typical, atypical, non-anginal)
-Heart failure demanding medical treatment

Study description

Background summary

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.

Study objective

N.A.

Study design

September 2020 start enrollment
December 2023 end enrollment
2026 end of follow-up last included patient

Intervention

-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 fysiological aspect.

Contacts

Public
Leiden University Medical Center
Claire Koppel

0031715297622
Scientific
Leiden University Medical Center
Claire Koppel

0031715297622

Eligibility criteria

Inclusion criteria

Patients with the diagnosis of:
-ACAOS
-Coronary artery from the pulmonary artery
-Coronary arteriovenous fistula

Exclusion criteria

-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)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2020
Enrollment:	210
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	15-07-2020
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 55795
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results

Summary results

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/