Multicenter Study on Coronary Anomalies in The Netherlands

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- Create a protocol including work-up, treatment and follow-up of ACAOS- Give an overview of the current practices involving ALCAPA, ARCAPA and CAVF

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Congenital cardiac disorders
Study type	Observational invasive

Summary

ID

NL-OMON55795

Source
ToetsingOnline

Brief title
MuSCAT

Condition

- Congenital cardiac disorders

Synonym
aberrant coronary artery, coronary artery anomaly

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Verzekeraar;alle onderzoeken zijn routine zorg

Intervention

Keyword: anomaly, coronary artery, diagnostics, work-up

Outcome measures

Primary outcome

Combined endpoint of (cardiac) death, myocardial infarction in anomalous vessel, re-intervention after surgical correction of ACAOS.

Secondary outcome

Quality of life according to the SF-36 questionnaire and the nature of the, if present, anginal complaints, i.e. typical, atypical or non-anginal, heart failure demanding medical treatment (mainly applicable in cases of ALCAPA/ARCAPA and CAVFs), exercise ability.

Study description

Background summary

Anomalous coronary arteries originating from the opposite sinus of Valsalva or opposite coronary artery (ACAOS), anomalous left or right coronary artery from the pulmonary artery (resp. ALCAPA, ARCAPA) and coronary arteriovenous fistulas (CAVF) are rare congenital conditions. In the *ESC guidelines for the management of grown-up congenital heart disease* ACAOS, ALCAPA, ARCAPA and CAVF are not even included for patients without concomitant congenital heart defects1. The existing guidelines that do discuss these defects in adults are mainly based on expert consensus and small or few trials1-3. For example, for interarterial courses of an ACAOS there is a class I, level B-NR indication for surgery in the new 2018 ACC/AHA guidelines2. The guideline states *surgery is recommended for AAOCA (=ACAOS) from the left sinus or AAOCA from the right sinus for symptoms or diagnostic evidence consistent with coronary ischemia attributable to the anomalous coronary artery*. They only speak of a recommendation and it is unclear what examinations have the most value in requiring the evidence of ischemia and thus making the decision to operate or not. So there is a need for a standardized work up and treatment protocol based on evidence from a larger study, especially for ACAOS with an interarterial course.

No protocol exists regarding the work-up, treatment and follow-up of our patient group. Many hospitals use different tools for diagnosis, possibly leading to different ways of treatment. We aim to create one national protocol using only the most important diagnostic tools for decision making. To decide which examinations are the most valuable in the diagnostic process we need to be able to compare the outcomes of different diagnostics per patient. This will provide for future patients a clear treatment path, thus keeping hospitals visits and hospital stays to a minimum and provide for clinicians an aid in caring for these rare anomalies.

Study objective

- Create a protocol including work-up, treatment and follow-up of ACAOS
- Give an overview of the current practices involving ALCAPA, ARCAPA and CAVF

Study design

This part of the larger MuSCAT study will be in a prospective setting. All referred patients with an ACAOS will receive work-up and follow-up according to a standard protocol created for this this study. For patients with ALCAPA, ARCAPA or CAVF only registry of hospital visits and events will take place. Inclusion will take place during 3 years with at least 2 years of follow-up.

Intervention

All examinations that will be done are currently routinely used for diagnostic purposes of ACAOS. Though, different hospitals use different examinations. All tests will be done according to their standard approved protocols. Overall, patients will get on average 1 examination more than would be done outside of this protocol.

Study burden and risks

The burden in the context of the study will comprise the following:
- At least 4 outpatient clinic visits in one of the participating tertiary hospitals. 1 intake, 3 after treatment decision/post-surgery (6 months, 12 months, 24 months).
- 1 or 2 coronary CT angiographies, ECG triggered, 0.5-1mm slices. 1 during work up, in case of surgery:1 at 6 months post-operative, however this will be at the treating doctors discretion
- 1 coronary angiography (CAG) during work up, in case of an interarterial course intravascular ultrasound (IVUS) and fractional flow reserve (FFR) measurements will also be done. In the LUMC an IFR will also be included. Only during work-up and at treating doctors discretion
- 1 transthoracic echocardiogram during work up.
- 1 or 2 examinations for ischemia detection, 1 during work up, in case of

surgery: 1 at 6 months post-operative, however this will be at the treating doctors discretion
- 3 SF-36 fill outs: 1 during work-up, 1 at 6 months after inclusion/surgery, 1 at 12 months after inclusion/surgery
- Other appointments or examinations will only be planned on indication

All procedures are routinely done in daily practice. Risks associated with participation are in general no greater than in other patients undergoing the same examinations. Only for the CAG with FFR and IVUS there might be a slightly increased risk of adverse events because of the abnormal coronary anatomy in ACAOS. However, in a recent study done by Driesen et al. no complications were made peri-procedural in 30 consecutive patients who underwent CAG with FFR and IVUS.

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

Presence of coronary artery anomaly, including anomalous coronary artery originating from opposite sinus or artery (ACAOS), coronary arteriovenous fistulas (CAVF), anomalous coronary arteries from pulmonary artery (ALPACA/ARCAPA)

Exclusion criteria

- A medical history of hemodynamically significant congenital heart defect other than an ACAOS, CAVF or ALCAPA/ARCAPA
- Proven coronary atherosclerotic disease

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-01-2021
Enrollment:	280
Type:	Actual

Ethics review

Approved WMO

Date:	04-05-2020
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

Approved WMO Date:	22-02-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
Approved WMO Date:	24-06-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 26172
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
Other	Netherlands Trial Register: NL8777
CCMO	NL69310.058.19
OMON	NL-OMON26172