Coronary Atherosclerosis in Type 1 Diabetes Mellitus

Published: 05-10-2023
Last updated: 07-04-2024

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Ethical review	Approved WMO
Status	Pending
Health condition type	Coronary artery disorders
Study type	Observational invasive

Summary

ID

NL-OMON56585

Source
ToetsingOnline

Brief title
COALA

Condition

- Coronary artery disorders
- Diabetic complications

Synonym
atheroma, Atherosclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Atherosclerosis, Coronary CT angiography, Diabetes Mellitus type 1

Outcome measures

Primary outcome

The main parameter to study will be total coronary plaque volume.

Secondary outcome

- Calcified plaque volume

- Non-calcified plaque volume

- Low-density non-calcified plaque volume

- Number and presence of high-risk plaque features, i.e.:

• Positive remodeling (RI>1.1)

• Low attenuation plaque (<=30 HU)

- Presence of obstructive stenosis (and number of vessels)

- Presence of any stenosis (and number of vessels)

- Lipid parameters

- CGM-derived metrics: TIR, TAR, TBR, glucose CV

Study description

Background summary

In type 1 diabetes mellitus (T1DM) patients, coronary heart disease (CHD) is a leading cause of morbidity and mortality. However, coronary plaque burden in younger T1DM patients remains inadequately explored and rationale regarding the optimal age to initiate lipid-lowering therapy (LLT) in T1DM is lacking. Furthermore, the impact of time spent above euglycemic range (TAR) is an emerging marker of poor glycemic control, while its impact as a risk factor for cardiovascular risk in T1DM remains to be established.

Study objective

The primary objective of this study is to evaluate the coronary plaque burden and plaque characteristics in young T1DM patients as compared with non-diabetic healthy controls, using coronary computed tomography angiography (CCTA). The secondary objective is to assess the association between chronic and intermittent hyperglycemia, as measured through glycated hemoglobin and TAR respectively, and captured by continuous glucose monitoring (CGM), on coronary plaque burden and plaque characteristics in T1DM patients.

Study design

Single center, observational, matched-pairs study.

Study burden and risks

The results of this study contribute to the discussion surrounding the optimal age to initiate lipid-lowering therapy (LLT) in T1DM. Moreover, the results will enhance our understanding of the impact of excessive hyperglycemia on coronary plaque burden and plaque characteristics in patients diagnosed with T1DM prior to clinically established CVD.

Participating T1DM patients in this study may benefit from increased awareness of their potentially elevated plaque burden, which can lead to the implementation of optimal risk-reducing medications (such as statins) and lifestyle interventions. Additionally, the utilization of CCTA imaging may provide incidental benefits by enabling early detection and treatment of extra-cardiac findings, including pulmonary malignancies. Decisions regarding the management of cardiac findings, such as significant coronary lesions, will be left to the discretion of the treating physician. Furthermore, the expected risk for participants is low. The most important risk in this study is radiation exposure. However, the maximum exposure related to CCTA imaging is 1.4 mSv. This is a low radiation exposure and even lower than the yearly dose of background radiation in the Netherlands. Furthermore, ionized contrast agents will be used during CCTA, which can be nephrotoxic and may elicit allergic reactions. However, in the GUTDM1 the prevalence of pre-existing eGFR <60ml/min is exceedingly rare, leading to a very low risk of nephrotoxicity. The control group has previously undergone CCTA as part of a recent study conducted at Amsterdam UMC. Consequently, no additional interventions will be administered to this group.
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Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Adult patients aged between 25 and 55 years old
- Received diagnosis of T1DM > 5 years ago
- > 2 years of available CGM data

Exclusion criteria

- Renal insufficiency, defined as eGFR < 30 ml/min
- Atrial fibrillation
- Prior and current use of statins
- Prior CVD events

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2023
Enrollment:	90
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	05-10-2023
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
CCMO	NL84960.018.23