Evaluating atherosclerotic disease progression in high-risk patients with diabetes mellitus type 2

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To describe the natural history of coronary artery disease in patients with diabetes mellitus type 2 through the use of serial CCTA, providing a comprehensive understanding of disease progression and its clinical implications over time.

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

Summary

ID

NL-OMON57547

Source
ToetsingOnline

Brief title
EVOLVE

Condition

- Coronary artery disorders
- Diabetic complications
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
clogged arteries of the heart, Coronary artery disease

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC

Source(s) of monetary or material Support: HORIZON-IHI en Novo Nordisk,Novo Nordisk,Philips

Intervention

Keyword: Atherosclerosis, Coronary-CT angiography, Diabetes mellitus

Outcome measures

Primary outcome

The progression of total coronary plaque volume

Secondary outcome

The following secondary parameters and endpoints will be studied:

• Presence of obstructive coronary artery disease on CCTA.

• Number of patients who underwent invasive angiography.

• Number of percutaneous coronary interventions (PCI) or Coronary Artery Bypass Grafting (CABG) procedures.

• If performed, results from additional stress testing (e.g. single photon emis-sion computed tomography, myocardial perfusion positron emission tomog-raphy, stress magnetic resonance imaging, stress echocardiography)

• Progression of calcified plaque volume (mm3).

• Progression of non-calcified plaque volume (mm3).

• Progression of low attenuation plaque volume (mm3)

• Changes in coronary artery calcium score (Agatston Units)

• Changes in CAD-RADS scores (as stated by the CAD-RADS expert consensus document):

• Changes in the number of high-risk plaque characteristics as defined by the CAD-RADS expert consensus document

• Changes in peri coronary fat attenuation index (HU).

• CT derived fractional flow reserve (CT-FFR)

• Biochemical biomarkers: e.g. total cholesterol, LDL, LDL, HDL, triglycerides, NT-proBNP, troponin, CRP, HbA1c, creatinine, serum glucose, lipoprotein a, apolipoprotein B, hemoglobin, leukocytes

• The number of cardiovascular events (all cause death, myocardial infarction (defined as the universal definition as established by the European Society of Cardiology (ESC), American College of Cardiology (ACC), American Heart Association (AHA) and the World health federation), Cerebrovascular accident (neurologic deficit lasting more than 24 hours or lasting less than 24 hours with a brain imaging study showing infarction, hospitalization for unsta-ble angina, target vessel revascularization, CAD related hospitalization).

Study description

Background summary

Patients with type 2 diabetes (T2D) face a significantly increased risk of coronary artery disease (CAD), with up to 80% ultimately dying from cardiovascular causes. This is driven by underlying mechanisms such as insulin resistance, hypertension, and dyslipidemia, which contribute to accelerated atherosclerosis and higher rates of adverse cardiovascular events. Early detection and management of CAD in T2D is crucial. Coronary computed tomography angiography (CCTA) biomarkers have been shown to predict plaque progression and major cardiovascular events (MACE) in T2D patients. Advancements in imaging technologies, such as photon-counting CT, have further improved diagnostic accuracy. This study aims to investigate the natural history of CAD in patients with T2D, integrating traditional risk factors, biochemical and imaging biomarkers to better predict plaque progression and MACE, providing a more comprehensive approach to cardiovascular risk management in this population.

Study objective

To describe the natural history of coronary artery disease in patients with diabetes mellitus type 2 through the use of serial CCTA, providing a comprehensive understanding of disease progression and its clinical implications over time.

Study design

multicentre, observational, prospective, cohort study

Study burden and risks

The results can contribute to improved CAD risk stratification in patients with stable chest pain identifying patients at high-risk for CAD. Participating subjects have no direct clinical benefits from participation. However, the expected risk is low. The most important risk is radiation exposure. Despite that, the maximum exposure related to CCTA is 1.4 mSv, which is lower than the yearly dose of background radiation. Ionized contrast agents will be used which can be nephrotoxic and may elicit allergic reactions.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Age over 18 years.
- Previous completion of a CCTA scan for CAD assessment.
- Diagnosed with Diabetes Mellitus type 2 and currently receiving glucose lowering treatment.
- Sufficient image quality of the CCTA scan at baseline (at least 2/3 vessels of sufficient quality
for assessment).

Exclusion criteria

- Inability to provide written informed consent.
- Presence of an unstable condition at time of baseline or follow up CT, including but not limited to:
1) Acute coronary syndrome
2) Hemodynamic instability.
3) Uncontrolled or recurrent ventricular tachy-arrhythmias.
- Ineligibility for CCTA due to:
1) Severe renal dysfunction (eGFR <= 30 mL/min/1.73m^2).
2) Known hypersensitivity or contraindication to CT contrast agents.
- Any other treatment or clinically relevant condition that could interfere with the conduct or interpretation of the study in the opinion of the investigator
- Inability or unwillingness to comply with the protocol requirements, or deemed by investigator to be unfit for the study.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	21-04-2025
Enrollment:	600
Type:	Anticipated

Ethics review

Approved WMO

Date:	12-05-2025
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	NL86138.018.24