The effect of Comprehensive Medical and Invasive Treatment strategy for patients with significant Left Anterior Descending artery disease on plaque progression

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The primary objective of the registry is:To analyse coronary artery disease progression with or without coronary artery bypass grafting.The secondary objective of the registry is:To report graft patency following bypass grafting of diffusely…

Ethical review	Not approved
Status	Will not start
Health condition type	Coronary artery disorders
Study type	Observational non invasive

Summary

ID

NL-OMON56133

Source
ToetsingOnline

Brief title
Plaque progression in diffusely diseased coronary arteries.

Condition

- Coronary artery disorders

Synonym
coronary artery disease, coronary heart disease

Research involving
Human

Sponsors and support

Primary sponsor: Zuyderland Medisch Centrum

Source(s) of monetary or material Support: Abbott Vascular

Intervention

Keyword: CABG, coronary artery disease, CT scan, optimal medical therapy

Outcome measures

Primary outcome

Disease progression and plaque burden. Patients will undergo a CT scan at baseline and at 1-year follow-up in order to estimate coronary calcification with the Agatston score and to analyse the progressions of stenotic lesions with a not pre-specified selection of methods.

Secondary outcome

Graft patency. Patients undergoing CABG will receive a baseline and follow-up (at 1-year) CT scan. There is no pre-specified scanning protocol.

Study description

Background summary

Coronary artery bypass grafting is a long-lasting treatment for symptomatic obstructive coronary artery disease. It is the treatment of choice in the presence of complex and extensive stenotic lesions and many consider it an attractive option for patients with diffusely diseased coronary arteries. What makes it appealing is the durability and disease-prevention capability of arterial grafts. Internal mammalian artery (IMA) grafts have 1-year mortality rates of 1.1%-4.5% (11-13) and 1-year MACE rates of ~3%-15%. Unfortunately, asymptomatic graft occlusion may be more common, and graft durability may decrease in the presence of diffuse coronary artery disease. In some cases LIMA failure may be as high as 7%-26%, with 26% observed in a special subset of diffusely diseased LAD*s. On the other hand, the evidence supporting the protective effects of mammalian arteries is growing but it remains unclear what its added value is when compared to state-of-the-art medical treatment.
The popularity of pharmacological management is rising, as several studies have failed to verify a mortality benefit after myocardial revascularization. This could be a result of recent developments in angina treatment and event

prevention. Not surprisingly, percutaneous and surgical interventions are more and more often delayed or avoided, especially in asymptomatic patients.

Study objective

The primary objective of the registry is:
To analyse coronary artery disease progression with or without coronary artery bypass grafting.

The secondary objective of the registry is:
To report graft patency following bypass grafting of diffusely diseased left anterior descending arteries.
To compare methods for plaque progression analysis.

Study design

Prospective multicenter real-world registry.

Study burden and risks

Applied treatments (pharmacological, interventional and surgical) are part of the current clinical practice. Contemporary CT scan protocols make use of radiation (1,5mSv) and contrast injection. According to the FDA the additional radiation risk is quite low.

Contacts

Public
Zuyderland Medisch Centrum

H. Dunantstraat 5
Heerlen 6419PC
NL
Scientific
Zuyderland Medisch Centrum

H. Dunantstraat 5
Heerlen 6419PC
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Stable coronary artery disease OR Hemodynamically stable patients with a Non-STE Acute Coronary Syndrome
Hemodynamically significant, diffuse LAD disease with involvement of the proximal segment (MEDINA 0.1.0 left main lesions allowed).
Age >= 18.
Signed informed consent.
Ability to tolerate and no plans to interrupt relevant medical treatment during the duration of the study and willing to comply with protocol required follow-up.

Exclusion criteria

Previous CABG
Prior anterior myocardial infarction with clear evidence of residual akinesia and/or dyskinesia
Extremely diseased LAD precluding intracoronary diagnostics or bypass grafting.
Renal dysfunction (GFR <30 ml/min/1.73m2)
Known contrast allergy
Severe aortic valve stenosis and/ or mitral valve regurgitation
Planned major surgery within the next 12 months
Extra-cardiac illness that is expected to limit survival to less than 1 year.
Pregnancy, planned pregnancy within the follow-up period, breastfeeding.

Study design

Design

Study type: Observational non invasive

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

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	100
Type:	Anticipated

Ethics review

Not approved

Date:	31-10-2023
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	NL84974.096.23