Comprehensive Medical and Invasive Treatment strategy for patients with significant Left Anterior Descending artery disease

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coronary artery disorders
Study type	Interventional

Summary

ID

NL-OMON51591

Source
ToetsingOnline

Brief title
COMMIT-LAD

Condition

- Coronary artery disorders

Synonym
angina pectoris, coronary artery disease

Research involving
Human

Sponsors and support

Primary sponsor: Zuyderland Medisch Centrum

Source(s) of monetary or material Support: Abbott Medical;Astra Zeneca

Intervention

Keyword: CABG, coronary artery disease, FFR, opmtial medical treatment, percutaneous coronary interventions

Outcome measures

Primary outcome

Primary outcome measure:

MACE: cardiovascular mortality, myocardial infarction (MI), stroke, unplanned revascularisation after the index procedure, or hospitalisation (>24 hours) due to cardiac ischaemia after the index procedure

Secondary outcome

Angina status, physical limitations and quality of life (measured by the SAQ summary score).

Study description

Background summary

Effective myocardial revascularization relies on the appropriate diagnosis of functionally significant coronary artery disease and the selection of the revascularisation modality. Besides the involvement of the left main stem (LM) and multivessel disease, a significantly diseased proximal left anterior descending artery (LAD) can also be considered for surgical revascularization. And although percutaneous coronary intervention (PCI) is also a viable option, medical experts agree that certain anatomical conditions and comorbidities, together with excellent patency of arterial grafts, favour surgical treatment in a significant number of cases. One of the numerous anatomical challenges is a diffusely diseased LAD, which is easy to miss but has a marked detrimental effect on PCI outcomes. In this special subgroup the utilisation of LIMA-grafts are associated with a protective effect against disease progression as well. But caution is also advised as diffusely diseased LADs are also known to have impaired graft patency.

We hypothesize that discrimination between focal and diffuse LAD disease is crucial to assign our patients to the treatment option from which they would gain the most benefit.

Study objective

The primary objective of the trial is:
To assess whether a non-surgical, fractional flow reserve (FFR) and optical coherence tomography (OCT)-guided treatment strategy* has a comparable outcome (MACE) with surgical revascularization of significant left anterior descending artery disease (LAD).

The key secondary objective of the trial is:
To compare the effect of the non-surgical, FFR- and OCT- guided treatment strategy on the angina status, physical limitations and quality of life (measured with the SAQ summary score) of our patients to the surgical arm.

Study design

Prospective, multicenter, randomized, open-label, comparative effectiveness clinical trial. Patients will be screened during the heart team discussions and randomized at the surgical centre after receiving the patient`s written informed consent.

Intervention

Two treatment strategies:
Group 1: Cardiac surgery (bypass grafting of the left anterior descending [LAD] coronary artery) and percutaneous coronary intervention of any other severe stenosis of the other two major coronary arteries.

Group 2: Percutaneous coronary intervention of short coronary artery stenoses, or pharmacological treatment of diffusely diseased LADs with percutaneous coronary intervention of any other severe stenosis of the other two large coronary arteries.

Study burden and risks

All treatments applied (pharmacological and nonpharmacological) are to be used within their respective indications. Any study requested combination of treatments is on-label and respects contemporary guidelines, recommendations and users* manuals.

Additional measurements required prior to the draw. The measurements are part of regular care, but are not always performed.

Participating in the study costs extra time.

The treatments used (also part of regular care) make use of radiation. In this study, the patient receives a total of about 10 mSv of radiation.

Within the framework of the study, patients will be contacted 4 times in 12 months. A call lasts ~15-20 minutes. Patients are sent short questionnaires about their quality of life and complaints 4 times in 12 months. The questionnaires can be completed very quickly and completion should not take longer than 30 minutes.

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

Stable coronary artery disease OR
Hemodynamically stable patients with a Non-STE Acute Coronary Syndrome AND
Hemodynamically significant LAD disease, as assessed by fractional flow reserve (FFR, <= 0.80) measurements; OR >90% lesion; OR non-invasive evidence of ischemia.

Eligibility for complete revascularization (defined as a British Cardiovascular Intervention Society [BCIS] revascularisation index >0.8). Please be aware that in the case of a diffusely diseased LAD and randomisation for the percutaneous arm, optimal medical therapy is seen as LAD-revascularization.

The local Heart Team must conclude that:
The LAD, irrespective of focal or diffuse disease, is suitable for both LIMA-LAD grafting and PCI (in the case of focal LAD disease).
Focally diseased LADs are suitable for PCI.
In the case of multivessel disease (2VD or 3VD) CABG not better than one of the study related treatments (for a medical reason e.g. porcelain aorta, poor conduits, comorbidities, frailty etc.). All NON-LAD lesions and coronary arteries must be suitable for FFR guided percutaneous coronary intervention.

Age >= 18 and <= 85 years

Signed informed consent.

Ability to tolerate and no plans to interrupt relevant medical treatment during the duration of the study.

Willing to comply with protocol required follow-up.

Exclusion criteria

Previous CABG
Any target lesion with in-stent restenosis within 1 year
Significant Left Main involvement
Significant valvular heart disease
Prior anterior myocardial infarction with clear evidence of residual akinesia and/or dyskinesia
Extremely calcified or tortuous vessels precluding LAD FFR measurement or OCT of the LAD.
Planned major surgery within the next 12 months
Extra-cardiac illness that is expected to limit survival to less than 1 years
Allergy or hypersensitivity to any of the study related drugs or devices (e.g. metals, antithrombotic agent etc.)

Active participation in another randomized trial
Unable to give informed consent or potential for noncompliance with the study protocol in the judgment of the investigator
Pregnant at the time of screening or unwilling to use effective birth control measures while dual antiplatelet therapy is required.

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-07-2022
Enrollment:	460
Type:	Actual

Ethics review

Approved WMO

Date:	06-05-2022
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	NL79703.096.21