Patients with Insulin-Treated Diabetes Mellitus and Coronary Artery Disease treated with Drug-Eluting Balloon Post Drug-Eluting Stent Therapy

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The aim of this study is to improve clinical outcomes in patients with insulin-treated DM after coronary stent placement in the treatment of coronary artery disease with drug-eluting balloon therapy after stent placement.

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

Summary

ID

NL-OMON48509

Source
ToetsingOnline

Brief title
IN-DEPTH

Condition

- Coronary artery disorders
- Diabetic complications

Synonym
athereosclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Amsterdam Cardiovascular Sciences beurs en onderzoeksgeld

Intervention

Keyword: drug-eluting balloon, drug-eluting stent, insulin treated diabetes mellitus, percutaneous coronary intervention

Outcome measures

Primary outcome

In-stent late lumen loss at 9 months follow-up, measured with optical coherence tomography, after PCI with drug-eluting stent followed by drug-coated balloon compared with in-stent late lumen loss after PCI with drug-eluting stent alone in a single lesion.

Secondary outcome

Device Success at 24 hours; Target Lesion Failure (composite of cardiac death, target vessel myocardial infarction, target lesion revascularization) at 9, 12 and 24 months.

Study description

Background summary

The prevalence of patients with Diabetes Mellitus (DM) is rising globally. One in three Dutch adults will develop DM type 2 during their life. Patients with DM are at high risk of atherosclerosis and coronary artery disease (CAD). Despite improved clinical outcomes after percutaneous coronary intervention (PCI) with drug-eluting stents (DES) in non-diabetic patients, numerous studies show poor outcomes in diabetic patients post stent placement.In non-DM patients, in-stent restenosis rates after PCI with DES are approximately 4-5% in the first year. In contrast, in DM patients treated with a DES, the in-stent restenosis rates exceeds 10% at one year follow-up. Moreover, the most

vulnerable are patients with insulin treated DM (ITDM), with repeat revascularization rates observed as high as 20% at one year follow-up. The difference in outcomes between diabetic and non-diabetic patients treated with PCI is primarily caused by increased in-stent restenosis caused by neointimal hyperplasia and neoatherosclerosis in the stented area. This results in higher repeat revascularization rates, but also in higher rates of target vessel myocardial infarction and cardiac mortality as some patients experience an acute coronary syndrome due to in-stent restenosis.

Study objective

The aim of this study is to improve clinical outcomes in patients with insulin-treated DM after coronary stent placement in the treatment of coronary artery disease with drug-eluting balloon therapy after stent placement.

Study design

This is a prospective, multicenter, randomized, single-blind investigator-initiated proof-of-concept study to evaluate the effect of drug-eluting ballon on luminal neoatherosclerosis and neointimal hyperplasia in patients with ITDM at 9 months post stent placement with optical coherence tomography (OCT).

Intervention

Standard treatment (drug-eluting stent placement) versus standard treatment with drug-eluting balloon in patients with insulin-dependent diabetes mellitus.

Study burden and risks

The treatment with the drug-eluting ballon could reduce the risk of in-stent restenosis, however this effect has not been established.
Risks of participating in this study are associated with the additional coronary angiography with OCT. The addition of radiation 0.8 mSv.

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

Insulin-treated diabetes mellitus with coronary artery disease, planned for percutaneous coronary intervention with drug-eluting stent.

Exclusion criteria

Unable to provide informed consent.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-11-2019
Enrollment:	50
Type:	Actual

Medical products/devices used

Generic name:	drug-eluting balloon
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	12-04-2019
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

ID: 24439
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL67496.018.18
OMON	NL-OMON24439