

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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24439

Source

Nationaal Trial Register

Brief title

IN-DEPTH

Health condition

Coronary artery disease in insulin-treated diabetic patients

Sponsors and support

Primary sponsor: None

Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

Late lumen loss at 9 months follow-up

Secondary outcome

In-stent neointimal hyperplasia volume, target lesion failure, stent thrombosis, angina pectoris

Study description

Background summary

Pilot trial randomizing 50 insulin-treated diabetic patients to either drug-eluting stent alone or drug-eluting balloon post drug-eluting stent implantation.

Study objective

In-stent restenosis rate is higher in diabetic than non-diabetic patients. A higher dose of sirolimus together with a more homogeneous spread will lower this rate of restenosis.

Study design

Index, 9 months, 12 and 24 months

Intervention

Drug-eluting balloon post drug-eluting stenting

Contacts

Public

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Scientific

Amsterdam UMC, location AMC
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Eligibility criteria

Inclusion criteria

Subject must be above 18 years of age, must have ischemic heart disease that requires PCI, has one or more target lesion(s) suitable for DES implantation, must have insulin-treated diabetes mellitus

Exclusion criteria

Subject present with STEMI. Target lesion is total occlusion, unprotected left main, located within a graft, in-stent restenosis, bifurcation with 2-vessel stenting, treatment plan includes stent overlapping

Study design

Design

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

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-09-2019
Enrollment:	50
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Ethics review

Positive opinion

Date: 21-08-2019

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 48509

Bron: ToetsingOnline

Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL7977
CCMO	NL67496.018.18
OMON	NL-OMON48509

Study results