Everolimus-eluting Bioresorbable Scaffolds for Treatment of Coronary Artery Disease in Patients with Diabetes Mellitus.
International, Multicenter, Observational, Prospective Registry Study

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26216

Source
Nationaal Trial Register

Brief title
ABSORB DM registry

Health condition

Diabetes Mellitus, Coronary Artery Disease

Sponsors and support

Primary sponsor: Isala Clinics Zwolle
Source(s) of monetary or material Support: Maatschap Cardiology Isala Hospital, Zwolle

Intervention

Outcome measures

Primary outcome

To evaluate the 1-year composite rate of patient oriented major adverse cardiac events (MACE) defined as a composite of:

•Death

•Myocardial infarction (MI)

•Ischemic-driven target vessel revascularization (TVR)

Secondary outcome

To evaluate the 1-year:

•Lesion oriented safety and efficacy composite of Cardiac death, MI, target lesion revascularization (TLR)

•Patient morbidity oriented endpoint of re-hospitalization due to unstable or crescendo angina pectoris.

•Device implantation success

•Procedure success

Study description

Background summary

International, multicenter, observational, prospective registry study to evaluate the performance of everolimus-eluting bioabsorbable scaffolds (EE-BRS) in patients with diabetes mellitus (DM).

500 patients will be enrolled in Belgium, Luxembourg and Netherlands. DM patient data providing from the France ABSORB register (a simultaneous parallel running 2000 all-comer patients register) will be pooled. Therefore the total population of ABSORB Diabetes is expected to be approximately 750 patients.

Patients will be included over 1 year, with a 1-year follow-up period.

Primary endpoint: A patient oriented composite endpoint of Death, MI, and target vessel revascularization (TVR) at 1 year.

Study objective

The ABSORB DM registry is designed to perform follow-up of all DM patients who have undergone ABSORB family placement. This international database will allow follow-up of all adverse events related to the product and/or the procedure.

Specifically, it will allow: Post-CE marking surveillance, with safety and clinical follow-up outcomes in the context of the use of the product in DM patients in a real-life clinical practice.

Study design

• First patient included: Q2 2015

• Last patient included: Q4 2016

• Completed 1 year FU: Q4 2017

Note: longer follow-up (3 and 5 years Fup) will be performed if funding allows

Intervention

PCI with implantation of at least one BVS (bioresorbable vascular scaffolding) in a de novo lesion located in a native non-grafted artery.

Contacts

Public
Dokter Stolteweg 96

Ilona Kalter
Zwolle 8025 AZ
The Netherlands
+31 (38)4262999
Scientific
Dokter Stolteweg 96

Ilona Kalter
Zwolle 8025 AZ
The Netherlands

+31 (38)4262999

Eligibility criteria

Inclusion criteria

•Patients aged 18 years or older.

•History of DM

•PCI with implantation of at least one BVS in a de novo lesion located in a native non-grafted artery.

Exclusion criteria

•Pregnancy

•Patients unable to provide informed consent

•Known ejection fraction <30%

•Life expectancy < 3 years

•Inability to take dual antiplatelet therapy for 12 months

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-04-2015
Enrollment:	500
Type:	Anticipated

Ethics review

Positive opinion

Date:	05-10-2015
Application type:	First submission

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
NTR-new	NL5338
NTR-old	NTR5447
Other	METC : 15.0242

Study results