eOPTIMA Registry

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The primairy objective of this study is to evaluate the safety and efficacy of the Janus OPTIMA stent in the treatment of the novo lesions in native cotronary arteries with a maximum lenght of 28 mm and a diameter of 2.5 - 4.0 mm

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

Summary

ID

NL-OMON32685

Source
ToetsingOnline

Brief title
eOPTIMA Registry

Condition

- Coronary artery disorders

Synonym
Neointimal hyperplasia, Stenosis

Research involving
Human

Sponsors and support

Primary sponsor: Sorin Biomedica Cardio - Vascular Therapy BU
Source(s) of monetary or material Support: Sorin Biomedica Cardio

Intervention

Keyword: atherosclerosis, coronary artery, DES, PCI

Outcome measures

Primary outcome

Incidence of adjudicated composite rate of cardiac death, MI, clinically driven

TLR at 6 months

Secondary outcome

Incidence of adjudicated composite rate of all death, MI, TVR at 6 months, 1

and 2 years

Adjudicated thrombosis rate according to ARC (Academic Research Consortium)

definition for each follow-up period; LLL (Late Lumen Loss) at 8 months

(subgroup analysis)

Study description

Background summary

This is a prospective, non-randomised, multicenter registry. The patients* clinical data will be recorded on a CRF accessible by Internet connection. eOPTIMA is a post market registry designed to evaluate, in everyday clinical practice, the performance of the device Janus OPTIMA in *real world* population. The *real world* registries are extremely important as eliminate the limitations related to the subjects* selection in the randomized coronary trials. The data collected through this electronic registry will allow us to compare the Optima results with those obtained in eJanus, being both *real world* registries.

Study objective

The primairy objective of this study is to evaluate the safety and efficacy of the Janus OPTIMA stent in the treatment of the novo lesions in native cotronary arteries with a maximum lenght of 28 mm and a diameter of 2.5 - 4.0 mm

Study design

It's a prospective, non-randomised, multicenter registry. The patients clinical

data will be recorded on a CRF accessible by Internet connection

Study burden and risks

The risks related to this trial are related to the procedure or the device but are not expected to be different than a normal standard procedure with a different kind of stent. The entolled subjects will be followed more accurately through clinical phone questionnaire, that could evidence the need of re-hospitalization, and have their pathology carefully followed through angiographic examination

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

Subjects >18 years of age
Subjects who are eligible for CABG surgery
Subjects diagnosed with the-novo coronary lesion(s) with a diameter stenosis >50% and <100% (visual estimation)

Exclusion criteria

Subjects involved in other clinical trials with any investigational drug or device
Women who are pregnant or who have the potential to become pregnant during the study
Subjects previously implanted with a coronary stent in the target lesion

Study design

Design

Study phase:	4
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

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

Medical products/devices used

Generic name:	Drug Eluting Stent
Registration:	Yes - CE intended use

Ethics review

Not approved

Date:	20-10-2008
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL23934.060.08