

CASE STUDY

Percutaneous coronary revascularization: a randomized comparison of a sirolimus-eluting stent with biodegradable polymer and an everolimus-eluting stent with a durable polymer

CATEGORISING

Kind

Research project involving living people

Type**Subtype**

Clinical trial with medical devices (according to ClinO-MD)

BACKGROUND

Drug-eluting coronary artery stents that release therapeutic agents locally, in a controlled fashion, have improved the safety and efficacy of percutaneous coronary interventions. This study compares the safety and efficacy of a sirolimus-eluting stent with a biodegradable polymer with that of an everolimus-eluting stent with a durable polymer. This is a prospective multicentre randomized controlled non-inferiority trial in patients who underwent percutaneous coronary intervention during routine clinical practice.

METHODS

Subjects aged ≥ 18 years, who have a symptomatic coronary artery disease (including chronic stable angina, silent ischemia, and acute coronary syndromes including NSTEMI-ACS and STEMI-ACS), are randomized for treatment either with the CE-marked Orsiro® stent system (sirolimus-eluting stent with a biodegradable polymer) or a CE-marked Xience PRIME® stent system (everolimus-eluting stent with a durable polymer). Primary endpoints are target lesion failure (defined as the composite of cardiac death, as well as target vessel myocardial infarction, and clinically driven target-lesion revascularization). No off-label use and no additional invasive or burdensome procedures in addition to those performed under the normal conditions of use of the two devices are described in the study protocol.

QUESTIONS OF THE CATEGORISER

Does the research project come under the scope of application of the Human Research Act?

Yes

BECAUSE

This project was based on a study protocol that defines the exact procedures to be used. It included a relatively large number of persons and was not based on individual cases ("method-driven search for generalizable knowledge", defined as research by HRA). Adults ("persons") who suffered from symptomatic coronary artery disease ("research concerning human diseases") were treated either with an Orsiro® stent system (sirolimus-eluting stent with a biodegradable polymer) or a Xience PRIME® stent system (everolimus-eluting stent with a durable polymer).

Is the research project a project involving living persons?

Yes

BECAUSE

Adults ("persons") who suffered from symptomatic coronary artery disease were included in this study.

Is the research project a clinical trial as defined by ClinO or ClinO-MD?

Yes

BECAUSE

The investigator randomly allocated ("prospectively assigned") adults ("persons") who suffered from symptomatic coronary artery disease to receive either an Orsiro® stent system (sirolimus-eluting stent with a biodegradable polymer) or a Xience PRIME® stent system (everolimus-eluting stent with a durable polymer). This was a ("health related intervention") therapeutic measure that assessed between-group difference in target-lesion failure ("to investigate its effect on health").

Does the trial involve investigating medicinal products (including combinations according to Art. 2 Para. 1 Letters f and g Medical Device Ordinance (MedDO) from the July 1, 2020)?

No

BECAUSE

Does the trial involve investigating a medical device (in vitro diagnostics excluded) or any other device as defined in Article 1 of the Medical Devices Ordinance (MedDO) (Status as of 26 May 2022)?

Yes

BECAUSE

The effects of the Orsiro® stent system and the Xience PRIME® stent system were investigated (both "medical devices") in this clinical trial.

Does the trial investigate an intervention that is neither a therapeutic product nor a transplant product, nor a product according to Art. 2a para. 2 Therapeutic Products Act (TPA) (Status from May 26, 2021), nor a transplant?

No

BECAUSE

Does the trial investigate gene therapy or a pathogenic organism?

No

BECAUSE

Does the medical device bear a conformity mark?

Yes

BECAUSE

The effects of the Orsiro® stent system and the Xience PRIME® stent system were investigated in this trial. Both passed the required conformity assessment procedure, and so both stent systems bear a CE mark (conformity mark).

In Switzerland, is it forbidden to make the medical device available on the market, to put it into service or to use it on a person?

No

BECAUSE

Is the device used in accordance with its instructions for use (same indications, contraindications, parameters or settings, precautions)?

Yes

BECAUSE

Adults who suffered from symptomatic coronary artery disease were treated either with the Orsiro® stent system (sirolimus-eluting stent with a biodegradable polymer) or the Xience PRIME® stent system (everolimus-eluting stent with a durable polymer). Both stent systems (medical devices) are indicated for improving coronary luminal diameter in patients with symptomatic heart disease caused by de novo native coronary artery lesions. This use complies with the instructions. Conformity mark available here (**Add link to PDF)