kofam

Koordinationsstelle Forschung am Menschen

BEISPIELSTUDIE

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

KATEGORISIERUNG

Gattung
Forschungsprojekt mit lebenden Personen

Art

Unterart
Klinischer Versuch mit Medizinprodukten (nach KlinV-Mep)

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 NSTE-ACS and STE-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.

CATEGORISER-FRAGEN

Fällt das Forschungsprojekt in den Geltungsbereich des Humanforschungsgesetzes?
Ja

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).

Handelt es sich bei dem Forschungsprojekt um ein Projekt mit lebenden Personen?
Ja

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

Handelt es sich bei dem Forschungsprojekt um einen klinischen Versuch im Sinne der KlinV oder der KlinV-Mep?
Ja

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").

Wird in der Studie ein Arzneimittel (einschliesslich Kombinationen nach Art. 2 Abs. 1 Bst. f und g Medizinprodukteverordnung (MepV) vom 1. Juli 2020) untersucht?
Nein

BECAUSE

Wird in der Studie ein Medizinprodukt (In-vitro-Diagnostika ausgenommen) oder ein anderes Produkt nach Artikel 1 der Medizinprodukteverordnung (MepV) (Stand am 26. Mai 2022) untersucht?
Ja

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

Wird in der Studie eine Intervention untersucht, die weder ein Heilmittel oder ein Transplantatprodukt, noch ein Produkt nach Art. 2a Abs. 2 Heilmittelgesetz (HMG) (Stand ab 26. Mai 2021) oder eine Transplantation ist?
Nein

BECAUSE

Wird in der Studie eine Gentherapie oder ein pathogener Organismus untersucht?
Nein

BECAUSE

Trägt das Medizinprodukt ein Konformitätskennzeichen?
Ja

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).

Ist die Bereitstellung auf dem Markt, die Inbetriebnahme oder die Anwendung des Medizinprodukt in der Schweiz verboten?
Nein

BECAUSE

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Wird das Medizinprodukt gemäss Gebrauchsanweisung angewendet?
Ja

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)

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