A Prospective Randomized, Multi-center, International, Open label, Clinical trial comparing the SELUTION DEB strategy versus DES strategy.

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1. At 1 year, to demonstrate non-inferiority for target vessel failure (TVF) of a treatment strategy with first line SELUTION SLR* DEB + provisional DES vs. systematic treatment with DES for the treatment of de novo coronary lesions.2. At 5-year…

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Coronary artery disorders
Study type	Interventional

Summary

ID

NL-OMON56719

Source
ToetsingOnline

Brief title
SELUTION DE NOVO

Condition

- Coronary artery disorders

Synonym
Ischemic heart disease - risk for restenosis

Research involving
Human

Sponsors and support

Primary sponsor: MedAlliance CardioVascular SA

Source(s) of monetary or material Support: Manufacturer: MedAlliance Cardio Vascular SA;Nyon;Switzerland

Intervention

Keyword: de novo coronary lesions, drug eluting balloon (DCB), drug eluting stent (DES), percutaneous coronary intervention (PCI)

Outcome measures

Primary outcome

• TVF (target vessel failure: cardiac death, target-vessel related myocardial

infarction (MI) or clinically driven target vessel revascularization (cd-TVR))

at 1 year

• TVF at 5 years

Secondary outcome

• At 30-days:

o safety endpoint (cardiac death, non-cardiac death, or any MI)

o efficacy (cd-TVR)

• TVF at 2, 3, and 4 years.

• Other endpoints at 30 days, 6 months, 1, 2, 3, 4 and 5 years

1. Any revascularization

a. Target lesion revascularization (TLR) - any and clinically driven

b. Target vessel revascularization (TVR) - any and clinically driven

c. A new lesion revascularization in a target vessel

d. Non-Target vessel revascularization

2. Myocardial Infarction

a. Peri-procedural MI

b. Target-vessel MI

c. Non-target-vessel MI

d. MI type (1 to 5) according to the 4th universal definition

3. Composite of cardiac death or target vessel MI

4. Lesion Thrombosis

5. All-cause mortality

6. Cardiac mortality

7. Non-cardiac mortality

8. Patient-oriented ARC-2 composite endpoint:

a. All-cause mortality

b. Any stroke

c. Any MI (includes non-target vessel territory)

d. Any revascularization

9. Stroke

10. BARC 3-5 Bleeding

11. Cost-effectiveness of DEB vs. DES after 12 months in selected countries

12. Net clinical benefit, a combination of freedom from TVF and/or BARC 3-5 bleeding

13. Device success defined as achievement of a final residual diameter stenosis of < 30% (site-reported), using the assigned device only

14. Lesion success defined as achievement of < 30% residual stenosis (sitereported), using any percutaneous method

15. Procedure success defined as achievement of a final diameter stenosis of<30% (site-reported) using any PCI method, without the occurrence of death, MI, or repeat target vessel revascularization during hospital stay

Study description

Background summary

Percutaneous Coronary Intervention (PCI) with stent implantation has been widely used as an alternative to medical or surgical treatment in selected subjects with symptomatic coronary artery disease. Although the use of metal coronary stents is rapidly increased owing to the advancement of safety and

efficacy of newer generation drug-eluting (DES), patients are not completely free from their inherent limitations such as stent thrombosis or restenosis including neoatherosclerosis and obligatory use of dual antiplatelet therapy (DAPT) with unknown optimal duration

Over the past 10 years, increasing interest has therefore been devoted to treatment options that would allow to *leave nothing behind*.
Drug-coated balloon (DCB) treatment follows the leaving nothing behind concept and therefore it is not limited by stent thrombosis and long-term DAPT because it delivers directly anti-proliferative drug which is coated to balloon after improving coronary blood flow with balloon angioplasty.
DCBs usually consist of semi-compliant balloons with an active drug embedded in a matrix. After inflation of the balloon, the drug is transferred to the vessel wall where is exerts its anti-proliferative action.

The SELUTION SLR* 014 PTCA is a Sirolimus-Eluting Balloon catheter for Percutaneous Transluminal Coronary Angioplasty (PTCA) procedures. The drug coating on the balloon part of the SELUTION SLR* 014 PTCA is a proprietary formulation, consisting of Sirolimus (also known as Rapamycin) as the Active Pharmaceutical Ingredient (API) and four excipients.

Its unique features allow controlled and effective elution of sirolimus into the vessel wall, and justify the DEB (drug eluting balloon) acronym, since other DCBs have a much shorter drug delivery time. The safety and efficacy of the SELUTION SLR* 014 DEB will be tested in this all-comer study, the Selution DeNovo trial.

Should the DEB + provisional DES prove to be the superior strategy, it has the potential to profoundly modify current PCI practice worldwide, since, despite its limitations, stent implantation has been the mainstay of PCI for the past 30 years.

Study objective

1. At 1 year, to demonstrate non-inferiority for target vessel failure (TVF) of a treatment strategy with first line SELUTION SLR* DEB + provisional DES vs. systematic treatment with DES for the treatment of de novo coronary lesions.

2. At 5-year follow-up, to demonstrate non-inferiority for TVF of the DEB + provisional DES vs. the systematic DES treatment strategy. If non-inferiority is achieved, a superiority test will be performed.

Study design

prospective randomized, multi-center, International, open label, clinical trial

Intervention

Subjects who satisfy all clinical and angiographic inclusion and exclusion criteria will be randomized in a 1:1 ratio to be treated for all the identified target lesions either with the SELUTION SLR* DEB + provisional DES strategy or the systematic DES strategy.

Study burden and risks

In this study patients are treated by CE-certified medical devices within their intended purpose. The medical devices used in the study, SELUTION SLR* Eluting Balloon (DEB) and the drug-eluting stents used in the study are commercially available and are already being already used in practice for the treatment of coronary heart disease.

The patients included in this study would have to undergo angioplasty anyway due to their underlying disease, otherwise the patients could not be included in this study due to the inclusion and exclusion criteria. be included in this study. The angioplasty procedure, including pre- and post-procedure examinations, will be performed as usual at the study center and therefore does not represent an additional burden.

After 1, 6, 12, 24, 36, 48 and 60 months, patients are asked questions about their state of health and medications taken during telephone contacts which will take about 20 mins each.

The medical risks for patients are not increased by participation in the study compared to treatment outside the study.
The risk of patients is minimally increased by the risk inherent to data collection. This risk has been mitigated by procedures that have been put in place to proctect the participating subjects' personal information.

Since the patients could be treated in the same way also outside the study, there is no direct personal benefit for the patients resulting from the study participation. The results of the study may contribute to determine what is the best treatment strategy for patients with coronary artery disease.

In addition, an independent Data Safety Monitoring Board will monitor safety of the subjects throughout the clinical investigation and a Clinical Events Committee will adjudicate adverse events as per the definitions in the CEC charter.

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

• Subject age is >= 18 years (or 21 according to countries legal age)

• Female subjects of childbearing potential have a negative pregnancy test <=7 days before the procedure or are using a contraceptive device or drug.

• Documented angina and/or positive functional testing or unstable angina or stabilized NSTEMI presentation, patients whose Index procedure is a staged procedure for non-culprit lesion PCI after Acute Myocardial Infarction (AMI) may be included in the absence of further documented ischemia/angina.

• Life expectancy >1 year

• Written informed consent by the subject for participation in the study

• One or more native target vessel (LAD, LCX or RCA) is considered to require intervention and is suitable for treatment of all lesions with either DEB + provisional stenting or with DES and is identified as such.

• The number of trial target lesions is not limited, but in the operator*s opinion, if the subject is randomized to the DEB arm, the likelihood of the subject requiring provisional stenting of any of the identified trial target lesions is < 30%, and if randomized to the systematic DES arm, all lesions are considered amenable to stenting.

• All target lesions: diameter between 2.0 and 5 mm, and diameter stenosis >50% and <100% with distal flow at least TIMI 2

Exclusion criteria

• Age < 18 years (or 21 according to countries legal age)

• Subject is pregnant or breast-feeding

• Definite or suspected clinically active covid-19 infection

• Subject is under judicial protection, tutorship or curatorship (for France only)

• Subject is unable to fully comply with the study protocol

• Contraindications to dual antiplatelet therapy, sirolimus or its analogues

• Presentation with STEMI

• Presentation with NSTEMI and ongoing chest pain or hemodynamic instability

• Presentation with Killip III (pulmonary oedema) or IV (cardiogenic shock)

• Chronic NYHA class III or IV heart failure prior to index PCI

• Known LVEF < 30% prior to index PCI

• Previous PCI of a trial target vessel at any time

• Previous PCI of a non-trial target vessel within 30 days

• Trial target lesion located in the left main or any arterial or venous graft

• Trial target lesion is chronic total occlusion (CTO) or in-stent restenosis (ISR)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-05-2024
Enrollment:	500
Type:	Actual

Medical products/devices used

Generic name:	SELUTION SLR 014 PTCA Sustained Limus Release Drug Eluting PTCA Balloon Catheter
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	08-04-2024
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
ClinicalTrials.gov	NCT04859985
CCMO	NL85239.042.23

Study results

Results posted: 02-09-2024

First publication
01-01-1900