Ultimaster NagomiTM Sirolimus Eluting Coronary Stent System in Complex PCI Subjects

Published: 04-10-2023
Last updated: 09-11-2024

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Coronary artery disorders
Study type	Observational non invasive

Summary

ID

NL-OMON53176

Source
ToetsingOnline

Brief title
Nagomi complex PMCF study

Condition

- Coronary artery disorders

Synonym
heart disease

Research involving
Human

Sponsors and support

Primary sponsor: Terumo
Source(s) of monetary or material Support: Sponsor: Terumo Europe N.V.

Intervention

Keyword: CE marked stent, Post-Marketing Clinical Follow-up

Outcome measures

Primary outcome

The primary endpoint is Target Lesion Failure (TLF) defined as the composite of cardiovascular death, target-vessel related myocardial infarction and clinically driven target lesion revascularization at 1-year post-procedure.

Secondary outcome

Secondary endpoints will be evaluated post-procedure, at discharge, at 30 days, 6 months, 1 year and 2 years.

• Delivery success

• Procedure success

• Lesion success

• Device success

• Target lesion failure (TLF)

• Patient oriented composite endpoint (POCE)

• All death and subclassifications

• All myocardial infarction and subclassifications

• All revascularization and subclassifications

• All stent thrombosis and subclassifications

• All strokes and subclassifications

• All bleedings and subclassifications

• Balance between bleeding (BARC 3-5) and thrombotic event (myocardial infarction and/or stent thrombosis)

• Utilization of cardiovascular health care resources

• Quality of Life (EQ-5D-5L)

• Angina status (Seattle Angina Questionnaire, SAQ-7)

• QCA of the index procedure angiogram for a subset of subjects with a Complex

Bifurcation Lesion (CBL)

Study description

Background summary

Advancement in Percutaneous Coronary Intervention (PCI) techniques such as improvements in imaging equipment, stent design and implantation technique as well as post-procedural pharmacological treatment have increased the number of subjects eligible for stent implantation with improved acute and long-term clinical outcomes.
Complex PCI subjects, defined by specific vessel and lesion characteristics, represent a subject subset in whom the PCI procedure is technically more challenging and associated with a higher risk for ischemic events. Complex subjects constitute a considerable segment of the subjects seen in daily PCI practice, but besides post-hoc subgroup analysis, no specific clinical study has been performed to assess the outcomes in this growing subject population. The NAGOMI COMPLEX PMCF (Post-Market Clinical Follow-up) study has been designed to expand the knowledge about outcomes with the Ultimaster NagomiTM sirolimus eluting coronary stent system (Ultimaster NagomiTM) in complex PCI subjects. The features for a complex PCI are based upon subgroup analysis of earlier published studies.

Study objective

The objectives of this clinical investigation are to evaluate the clinical outcomes of the Ultimaster NagomiTM coronary drug eluting stent and to determine treatment practices and economic impact in complex subjects eligible for a percutaneous coronary intervention.

The primary objective is to evaluate the clinical outcomes of the Ultimaster NagomiTM stent in complex subjects at high ischemic risk eligible for a percutaneous coronary intervention.

The secondary objectives are to assess:
• The deliverability of the Ultimaster NagomiTM stent.

• The balance between bleeding events and thrombotic events.
• Patient-reported outcomes (quality of life and angina status).
• Economic impact.
• Procedural angiographic outcomes by Quantitative Coronary Angiography (QCA) in subjects with a bifurcation lesion.

Study design

The study is a prospective, multi-center, post-market clinical follow-up study

Study burden and risks

Since only data are collected as part of our study, there are no medical risks associated with your participation in the study beyond the usual risk of a stenting procedure.
Neither the treatment that has been proposed nor the diagnostic and monitoring procedures for your clinical situation go beyond good medical practice. All procedures will be as per standard hospital routine practice, and selected sites are experienced in interventional procedures and in particular with patients that have a medical condition. Therefore, participation in this study does not impose additional risk to the participant while it will provide additional knowledge of the treatment for the condition that might benefit future patients.

Contacts

Public
Terumo

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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1) Age >= 18 years 2) Subject has been informed of the nature of the study and agrees to its provisions, has provided written informed consent as approved by the Institutional Review Board/Ethics Committee of the respective clinical site 3) Ischemic heart disease with an indication for a PCI with, if available in the hospital, Heart Team consensus for a PCI procedure 4) Intention to treat all lesions requiring a PCI with the Ultimaster NagomiTM stent 5) Subject meets >= 1 of the complex procedure criteria: a) Multivessel PCI defined as >= 2 native coronary arteries and/or venous or arterial bypass grafts treated with a stent b) >= 3 stents implanted c) >= 3 lesions treated d) Complex bifurcation lesion defined as true bifurcation lesion (Medina 1.1.1, 1.0.1 or 0.1.1) with a side branch diameter >= 2.5 mm plus one of the following: i) side branch disease > 10 mm ii) calcified lesion iii) thrombotic lesion e) Bifurcation lesion implanted with two stents f) Total stent length implanted > 60 mm g) Chronic total occlusion defined as a 100% occlusion with antegrade TIMI 0 flow with at least a 3-month duration h) Left main stenting (main stem and/or bifurcation) i) Instent restenosis j) Severe calcified lesion with use of atherectomy, lithotripsy or cutting balloon

Exclusion criteria

1) Any surgery requiring general anaesthesia, comorbidity or indication likely necessitating the discontinuation of dual anti-platelet therapy before the recommended duration of dual anti-platelet therapy per the ESC or national guidelines 2) Hypersensitivity or contraindication to aspirin, heparin, L605 cobaltchromium alloy, sirolimus or its structurally related compounds, lactide polymers or caprolactone polymers that cannot be pre-medicated 3) Known contrast sensitivity that cannot be premedicated 4) Pregnant and breastfeeding women 5) Life expectancy < 1 year for any cardiac or non-cardiac cause 6) Participation in another clinical study that has not yet completed its primary endpoint 7) Earlier enrolment in the NAGOMI COMPLEX PMCF STUDY 8) Unlikely to

be available for follow-up during the duration of the study (2 years)

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-11-2023
Enrollment:	580
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	04-10-2023
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	16-07-2024
Application type:	Amendment
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	NL84445.100.23