The TARGET-IV NA Trial: Multicenter Randomized Assessment of the Firehawk® rapamycin TARGET eluting cobalt chromium coronary stent system - North American Trial

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To demonstrate safety and efficacy of Firehawk® rapamycin eluting stent system in comparison to currently approved 2nd generation DESin wide clinical use.

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

Summary

ID

NL-OMON51176

Source
ToetsingOnline

Brief title
TARGET-IV NA trial

Condition

- Coronary artery disorders

Synonym
coronary heart disease, ischemic heart disease

Research involving
Human

Sponsors and support

Primary sponsor: Shanghai MicroPort Medical (Group) Co Ltd
Source(s) of monetary or material Support: Industry: MicroPort

Intervention

Keyword: Drug eluting stents, Firehawk stent system, Percutaneous coronary intervention

Outcome measures

Primary outcome

Target Lesion Failure (TLF, defined as the composite of cardiac death, target

vessel-related myocardial infarction*, or ischemia-driven target

lesion revascularization) at 12 months.

For the primary endpoint myocardial infarction (including periprocedural

MI*s) will be assessed per the 4th Universal Definition of

Myocardial Infarction.

The primary endpoint will be assessed for the following subgroups at

12 months:

* Geographic region (US versus outside US)

* Geographic region (North America versus Rest of the World)

* Sex (male / female)

* Diabetes

* Multivessel disease

* Presence versus absence of ACS

* Overlapping stents

* Age (Above versus below 75 years)

* Ethnicity

* Race

* Bifurcation lesion

* Long Lesion (>=30 mm)

* Small Vessels (RVD <=2.5mm)

* Defined as a myocardial infarction that cannot be clearly attributed to a

non-target vessel

Secondary outcome

Secondary endpoints will be evaluated at 12 months and yearly thereafter until

5 years (except as specifically noted):

1. TLF at 30 days, 6 months, and 2-5 years

2. Target vessel failure (TVF; defined as the composite of cardiac death,

target vessel-related MI*, or ischemia-driven targetvessel revascularization

3. Major adverse cardiac events (MACE) defined as the composite of cardiac

death, any MI or ischemia-driven TLR, and stent thrombosis

4. All-cause mortality

5. Cardiac death

6. Q-wave MI

7. Non Q-wave MI

8. Any MI

9. Target vessel MI

10. Any revascularization

11. Ischemia-driven TLR

12. Probable stent thrombosis

13. Definite stent thrombosis

*Peri-procedural Myocardial Infarction (MI) as well as spontaneous MI*s will be adjudicated based on the Fourth Universal definition of

Performance endpoints:

• Device Success (Lesion Basis): Successful delivery and deployment of the study stent at the intended target lesion and successful withdrawal of the delivery system with attainment of final in-stent residual stenosis of less than 30% by QCA (by visual estimation if QCA unavailable).

• Lesion Success (Lesion Basis): Successful delivery and deployment of any stent at the intended target lesion and successful withdrawal of the delivery system with attainment of final in-stent residual stenosis of less than 30% by QCA (by visual estimation if QCA unavailable).

• Procedure Success (Patient Basis): Achievement of final instent residual stenosis of less than 30% by QCA (by visual estimation if QCA unavailable) with successful delivery and deployment of at least one study stent at the intended target lesion and successful withdrawal of the delivery system for all target lesions without the occurrence of cardiac death, target vessel MI or repeat TLR during the hospital stay (maximum of 7 days). In dual target lesion setting both lesions must meet clinical procedure success criteria to have a patient level procedure success.

Study description

Background summary

A new Drug Eluting Stent (DES) is made available within the current study. A stent is a medical device that is inserted into a blood vessel in the heart to help open blockages.. A drug eluting stent (DES) is a special stent that releases a drug which helps prevent blockages from coming back (a condition called restenosis).
Microport*s new DES system is called the Firehawk* rapamycin target eluting cobalt chromium coronary stent system, hereafter called the Firehawk* stent. The purpose of this study is to compare the efficacy (how well it works) and safety of the Firehawk* stent to other drug eluting stent (DES) systems. These other DES systems (containing the drugs everolimus, sirolimus or zotarolimus) are already approved for use in Europe and would be used by your study doctor to treat your condition in routine practice.

Study objective

To demonstrate safety and efficacy of Firehawk® rapamycin eluting stent system in comparison to currently approved 2nd generation DES
in wide clinical use.

Study design

TARGET-IV NA trial is a prospective, multicenter, 1:1 randomized (Firehawk® vs. 2nd generation DES), trial. Patients will be stratified by enrolling site, by whether they present with acute coronary syndrome versus stable coronary artery disease and by whether they they have a pre-existing medically treated diabetes.

This is a prospective, multi-center, partially blinded study, 1: 1 randomized non-inferiority trial comparing the Firehawk® stent system (treatment arm) with commercially approved contemporary 2nd generation DES (control arm). Subjects in the control arm can be treated with one of several commercially approved contemporary stents, such as everolimus-eluting stents (Xience family - Abbott Vascular, Promus family- Boston Scientific, Synergy - Boston Scientific) and zotarolimus-eluting stents (Resolute / Onyx family and Endeavour - Medtronic) or sirolimus-eluting stents (Orsiro-Biotronik).

Approximately 1616 subjects will participate in the study to undergo PCI for angina (stable or unstable), silent ischemia (in the absence of symptoms, a visually estimated stenosis of the target lesion diameter of >=70%, a positive noninvasive stress test, FFR <=0.80, iFR <0.90, or rFR <0.89 must be present) or myocardial infarction without ST-segment elevation (NSTEMI), and STEMI (>24 hours from initial presentation and in whom enzyme levels have peaked). At 50%

of subjects will be recruited in the US out of 60% in North America (US and Canada). Additional subjects may be recruited in Europe and Israel. A maximum of 150 patients will be included per center. patients randomized will be followed for 5 years for major clinical events, as described in section 7.3.3.1 of the protocol.

Intervention

PCI with Firehawk® stent system

Study burden and risks

All eligible subjects have an indication for cardiac catheterization according to current guidelines. There is extensive clinical and commercial experience worldwide with cardiac catheterization and interventional procedures and it is expected that the surgical and procedural risks will not be significantly different in this clinical trial.
There are no guaranteed benefits from participation in this study. However, all subjects will have more intense clinical follow-up compared with standard practice, which may be beneficial to the long-term clinical outcome of the study participants. It is also possible that the Firehawk® rapamycin eluting stent system reduces the risk for late and very late stent thrombosis, a complication associated with MI and death.

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

1) Age >= 18 years.
2) Patient understands the trial requirements and treatment procedures and provides written informed consent prior to any trial-specific tests or treatment
3) Patients with an indication for PCI including angina (stable or unstable), silent ischemia (in absence of symptoms a visually estimated target lesion diameter stenosis of >=70%, a positive non-invasive stress test, or a positive coronary physiology test (e.g. FFR<=0.80 or iFR<0.90 or rFR <= 0.89 must be present), NSTEMI, or recent STEMI (STEMI >24 hours and in whom enzyme levels have peaked). For STEMI the time of presentation to the first treating hospital, whether a transfer
facility or the study hospital, must be >24 hours prior to randomization and enzyme levels (CK-MB or Troponin)
demonstrating that either or both enzyme levels have peaked
4) Patient is willing to comply with all protocol-required follow up evaluations.
Angiographic Inclusion Criteria (visual estimate):
a. Target lesion(s) must be located in a native coronary artery with visually estimated diameter of >=2.25 mm to <=4.0 mm and
up to 44 mm in length.
b. The coronary anatomy is deemed likely to allow delivery of a study device to the target lesion(s).
c. Complex lesions are allowed including calcified lesions (lesion preparation is allowed and strongly recommended with current approved devices (e.g. scoring/cutting balloon and rotational/orbital atherectomy), multivessel disease, CTO,
Confidential and Proprietary bifurcation lesions (except planned dual stent implantation), ostial lesions, tortuous lesions, and protected left main lesions.
4) Overlapping stents are allowed

Exclusion criteria

1) STEMI within 24 hours of initial time of presentation to the first treating hospital, whether at a transfer facility or the study
hospital or in whom enzyme levels (either CK-MB or Troponin) have not peaked.
2) PCI within the 24 hours preceding the baseline procedure.
3) History of stent thrombosis.
4) Cardiogenic shock (defined as persistent hypotension (systolic blood pressure <90 mm/Hg for more than 30 minutes) or requiring pressors or hemodynamic support, including IABP.
5) Subject is intubated.
6) Known LVEF <30%.
7) Subject has a known allergy to contrast (that cannot be adequately pre-medicated) and/or the trial stent system or any protocol-required concomitant medications or devices (e.g. cobalt chromium alloy, stainless steel, sirolimus, everolimus and zotarolimus, or structurally related compounds, polymer, all P2Y12 inhibitors, or aspirin).
8) Planned surgery within 6 months.
9) Subject has an indication for chronic oral anticoagulant treatment (with either vitamin K antagonists or novel anticoagulants - NOACs)
10) Calculated creatinine clearance <30 mL/min using Cockcroft-Gault equation (<40 mL/min for Subjects participating in the,angiographic follow-up sub-study).
11) Hemoglobin <10 g/dL.
12) Platelet count <100,000 cells/mm3 or >700,000 cells/mm3.
13) White blood cell (WBC) count <3,000 cells/mm3.
14) Clinically significant liver disease.
15) Active peptic ulcer or active bleeding from any site.
16) Other serious medical illness with a life-expectancy < 24 months (e.g. cancer, severe heart failure, severe lung disease).
17) A planned procedure that may cause non-compliance with the protocol or confound data interpretation.
18) Participation in another investigational drug or device trial that has not yet reached its primary endpoint and that may interfere with protocol compliance or confound data interpretation (as per the opinion of the investigator); or intent to participate in another investigational drug or device trial within 12 months.
19) Intention to become pregnant within 12 months (women of child-bearing potential who are sexually active must agree to use contraceptives from the time of enrollment through 12 months post procedure.
20) Pregnancy or nursing (women of child-bearing potential must have a pregnancy test within 7 days prior to the index procedure).
21) Any co-morbid condition that may cause non-compliance with the protocol (e.g. dementia, substance abuse, etc.)
22) Subject has received an organ transplant or is on a waiting list for an organ transplant.
23) Subject is receiving oral or intravenous immunosuppressive therapy or has

known life-limiting immunosuppressive or autoimmune disease (e.g., HIV). Corticosteroids are allowed.

Angiographic Exclusion Criteria:
1) Unprotected left main interventions
2) Bifurcation lesions with intended dual stent implantations
3) DES restenotic lesions
4) Prior PCI in the target vessel in the 12 months prior to enrollment
5) Any lesion in the target vessel that is likely to require PCI within 12 months
6) Stent lengths >36mm for diameters 2.0 mm and 2.25 mm (i.e., very long thin stents).
7) Lesion with intended >= 3 stent implantation

Note:
1. A maximum of 2 target vessels and up to 2 target lesions per vessel may be treated. Lesions which are up to 10 mm apart and can be covered by a single stent are considered one lesion.
2. Randomization will take place after the first target lesion has been crossed with a wire and any lesion preparation (such as pre-dilation) has been successfully achieved.
3. Lesions not meeting angiographic criteria may be treated as non-target lesions but must meet the following conditions:
* Be located in non-target vessels
* Treated successfully prior to randomization, >24 hrs. prior to randomization or if performed during the index procedure must be successful and uncomplicated (<50% visually estimated residual diameter stenosis, TIMI Grade 3 flow, no dissection >= NHLBI type C, no perforation, no persistent ST segment changes, no prolonged chest pain, no TIMI major or BARC type 3 bleeding).
4. All target lesions are to be treated during baseline procedures and planned staged procedures are not allowed. However, if during the procedure staging becomes necessary (for example due to excessive contrast load) the staged procedure should be completed within 6 weeks and should be performed with the assigned (randomized) stent.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-02-2022
Enrollment:	300
Type:	Actual

Medical products/devices used

Generic name:	Firehawk® rapamycine TARGET eluting kobaltchroom coronaire stentsysteem
Registration:	No

Ethics review

Approved WMO Date:	22-12-2021
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	08-06-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	18-09-2024
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NCT04562532
CCMO	NL77897.000.21