Target All Comer: A prospective multicenter randomized post market trial to assess the safety and effectiveness of the Firehawk* rapamycin target eluting cobalt chromium coronary stent system (Firehawk* stent system) for the treatment of atherosclerotic lesion(s)

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This scientific study is intended to compare the safety and effectiveness of two stents, the Firehawk* stent and the XIENCE* stent. Both stents release a medicine. This reduces the odds of the blood vessel narrowing again. The Firehawk* stent is...

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

Summary

ID

NL-OMON47351

Source
ToetsingOnline

Brief title
TARGET All Comer

Condition

- Coronary artery disorders

Synonym
Stenosis of one or more of the vessels of the heart / Cardio vascular stenosis

Research involving
Human

Sponsors and support

Primary sponsor: Shanghai MicroPort Medical (Group) Co., Ltd.
Source(s) of monetary or material Support: MicroPort Medical B.V.

Intervention

Keyword: All Comer, Comparison of two stents, Multi centers in Europe, Non inferiority trial

Outcome measures

Primary outcome

The primary endpoint is the 12-month target lesion failure (TLF) rate, defined

as a composite of cardiac death, myocardial infarction (not clearly

attributable to a non-target vessel), or ischemia-driven revascularization of

the target lesion (ID-TLR) within 12 months.

Secondary outcome

Secondary endpoints:

Clinical endpoints measured in hospital and at 30 days, 3 months (OCT sub study

only), 6 months, 12 months, 2 years, 3 years, 4 years, and 5 years:

* Target Lesion Revascularization (TLR) rate (ischemia-driven TLR, and any TLR)

* Target Lesion Failure (TLF) rate (primary endpoint at 12 months)

* Target vessel revascularization (TVR) rate (ischemia-driven TVR, and any TVR)

* All revascularization rate

* Target Vessel Failure (TVF) rate (composite of cardiac death, any myocardial

infarction [MI] not clearly attributable to a non-target vessel, or any

ischemia-driven revascularization of the target vessel)

* MI (Q-wave and non*Q-wave) rate

* Target vessel MI

* Cardiac death rate

* Non-cardiac death rate

* All death rate

* Cardiac death or MI rate

* All death or MI rate

* All death/MI/TVR rate

* Stent thrombosis rates (by Academic Research Consortium [ARC] definitions)

Peri-procedural endpoints:

* Technical device success rate

* Clinical procedural success rate

Angiographic endpoints at 13-month (time window 12*14 months post index procedure) measured by QCA:

* In-stent late loss (mm) (powered endpoint)

* In-stent and in-segment percent diameter stenosis (%DS)

* In-segment late loss (mm)

* In-stent and in-segment binary restenosis rate (%)

* In-stent and in-segment minimum lumen diameter (MLD)

Optical Coherence Tomography (OCT) endpoints at 3-month post-index procedure :

o Neointimal thickness (µm) (powered endpoint)

o Mean/Minimal Stent diameter/area (mm/mm2)

o Mean/Minimal Lumen diameter/area (mm/mm2)

o Lumen volume (mm3)

o Stent volume (mm3)

o Mean neointimal hyperplasia area/volume (mm2/mm3)

o In-stent neointimal hyperplasia volume obstruction (%)

o Percentage of incomplete apposed struts (%)

o Uncovered strut rate

o Malapposed strut rate

o Malapposed and uncovered strut rate

Study description

Background summary

One or more narrowings in one or more coronary arteries that are reducing blood flow to the heart muscle. To prevent damage to your heart muscle, the narrowing(s) must be treated. This is usually done via a procedure called percutaneous angioplasty. To do so, a thin tube (catheter) is inserted into your arteries via the groin or wrist. X-rays are then used to make the coronary artery visible. First a balloon is placed in the narrowing in the coronary artery to open the artery, and a small metal tube called a stent is left in place to prop the artery open.

The stent that is placed remains in your body and becomes a permanent part of the artery. Stents have been used for years to treat narrowing of coronary arteries and are not unique to this study. The procedure itself is a standard procedure for this condition.

Study objective

This scientific study is intended to compare the safety and effectiveness of two stents, the Firehawk* stent and the XIENCE* stent. Both stents release a medicine. This reduces the odds of the blood vessel narrowing again.

The Firehawk* stent is covered with a layer containing the medicine Rapamycin along with a polymer to hold and release the drug. This layer, also called a 'polymer layer', is 100% biodegradable; after the drug is released, the polymer is slowly absorbed by your body and disappears entirely from the stent.

The XIENCE* stent is covered with a thin layer of 'polymer' containing the medicine Everolimus. This polymer layer is not biodegradable and remains on the stent permanently.

There may be advantages to a stent with a biodegradable polymer, because it is fully absorbed by your body and does not remain on the stent. The medicine is only released for a limited time (up to 3 months for the Firehawk*).

Both stents have a CE mark (approval for use in patients from authorities) and meet the applicable regulations within the European Union. This study is being performed to prove both stents are equally good.

Study design

This is a European, prospective, multicenter, 1:1 randomized (Firehawk* to Xience TM family EES), controlled, open-label, non-inferiority trial in a *Real-world, all-comer* population.

Clinical follow-up will be required at 30 days, 6 months, 12 months, 2 years, 3 years, 4 years, and 5 years after the index procedure.
Subjects who are enrolled but who do not receive a study stent (i.e., the XienceTM family EES control stent or the Firehawk* stent), will be followed through 12 months only.

Sub studies:
Angiographic (QCA) sub study: the first 176 consecutive subjects who consent to participate in the angiographic sub study will undergo angiographic follow-up at 13 months. The QCA sub study will be executed in selected sites in United Kingdom, France, Spain, Italy, Belgium, Netherlands, Poland, Denmark and possibly other European countries.

Optical Coherence Tomography (OCT) sub study: the first 50 consecutive subjects who consent to participate in the OCT sub study will undergo OCT assessment and clinical follow-up at 3 months post index procedure. The OCT sub study will be performed in 3-5 pre-selected sites.

Intervention

828 Subjects will receive the Firehawk stent and 828 subjects will receive the Xience stent. Approximately 25 sites in Europe will participate.

Study burden and risks

The potential risks and undesirable effects resulting from the use of these stents are the same as for other stents. The potential risks are not specific for participation in this clinical research.

The potential risks for pregnancy associated with this treatment are unknown, and use of adequate contraception during the first year of the study is mandatory for women of childbearing potential.

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

CI1. Subject must be at least 18 years of age
CI2. Subject understands the trial requirements and the treatment procedures and provides written informed consent before any trial-specific tests or procedures are performed
CI3. Subject is eligible for percutaneous coronary intervention (PCI)
CI4. Subject has symptomatic coronary artery disease or silent ischemia with objective evidence of ischemia, or acute coronary syndromes, and qualifies for PCI
CI5. Subject is willing to comply with all protocol-required follow-up evaluations;Angiographic inclusion criteria:
AI1. Subject has one or more coronary artery stenosis of *50% in a native coronary artery or in a saphenous or arterial bypass conduit with visually estimated reference vessel diameter (RVD) *2.25 mm and *4.0 mm
AI2. Coronary anatomy is likely to allow delivery of a study device to the target lesions(s)

Exclusion criteria

CE1. Subject has a known allergy to contrast (that cannot be adequately pre-medicated) and/or the trial stent system or protocol-required concomitant medications (e.g., cobalt chromium alloy, stainless steel, sirolimus, everolimus or structurally related compounds, polymer or individual components, all P2Y12 inhibitors, or aspirin)
CE2. Planned surgery within 6 months after the index procedure
CE3. Subject has one of the following (as assessed prior to the index procedure):
o Other serious medical illness (e.g., cancer, congestive heart failure) with estimated life expectancy of less than 12 months.
o Current problems with substance abuse (e.g., alcohol, cocaine, heroin, etc.)
o Planned procedure that may cause non-compliance with the protocol or confound data interpretation.
CE4. Subject has a history of bleeding diathesis or coagulopathy or will refuse blood transfusions
CE5. Subject is participating in another investigational drug or device clinical trial that has not reached its primary endpoint, or that, in the opinion of the investigator, may cause non-compliance with the protocol or confound data interpretation.
CE6. Subject intends to participate in another investigational drug or device clinical trial within 12 months after the index procedure
CE7. Subject with known intention to procreate within 12 months after the index procedure (women of child-bearing potential who are sexually active must agree to use a reliable method of contraception from the time of screening through 12 months after the index procedure)
CE8. Subject is a woman who is pregnant or nursing (a pregnancy test must be performed within 7 days prior to the index procedure in women of child-bearing potential);Note: No restrictions are placed on the total number of treated lesions, treated vessels, lesion length, or number of stents implanted.

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-02-2016
Enrollment:	500
Type:	Actual

Medical products/devices used

Generic name:	Firehawk stent system or Xience stent
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	20-01-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	31-05-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-07-2016

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-07-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-02-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-01-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-03-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NCT02520180
CCMO	NL55050.029.15