A Prospective, Multi-Center, Non-randomized, Single arm, Open label, Pivotal Study to Evaluate the Safety and Effectiveness of the NovaCross* Micro-catheter in Facilitating Crossing Chronic Total Occlusion (CTO) Coronary Lesions.

Published: 05-08-2015
Last updated: 21-04-2024

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

Summary

ID

NL-OMON41722

Source
ToetsingOnline

Brief title
NT-CLP-01

Condition

- Coronary artery disorders
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
PCI CTO, stenosis

Research involving
Human

Sponsors and support

Primary sponsor: Nitiloop Ltd.
Source(s) of monetary or material Support: Nitiloop Ltd.

Intervention

Keyword: NT-CLP-01

Outcome measures

Primary outcome

Primary Safety Endpoint:

30 day MACE, defined as the composite of death, myocardial infarction (MI), or urgent revascularization (target vessel revascularization (TVR) or urgent coronary artery bypass surgery (CABG)).

Primary Effectiveness Endpoint:

Intra-procedural technical success Defined as the ability of the NovaCross* microcatheter to successfully facilitate placement of a guidewire beyond a native coronary chronic total occlusion (CTO) in the true vessel lumen.

Secondary outcome

Secondary endpoints:

The following objectives are pre-specified but are not intended to support product labeling:

1) The ability to cross the lesion with a guidewire in the true lumen,

effectively dilate the CTO lesion, and place a coronary stent with residual

lumen stenosis of less than 30% while restoring antegrade TIMI 3 flow.

2) The ability of the NovaCross* micro-catheter to facilitate a guidewire

successfully penetrating the proximal cap of the CTO.

3) The effectiveness of the extendable portion in intra-CTO microcatheter

crossability.

4) The ability to have full visualization of the NovaCross during the CTO

procedure.

5) Assess the usability of the NovaCross* by the operator.

6) Device-related perforation at the site of target coronary lesion and/or its

proximal reference segment.

Study description

Background summary

The purpose of this trial is to evaluate the safety and effectiveness of the NovaCross* micro-catheter when used to facilitate crossing of Chronic Total Occlusion (CTO) lesions in coronary arteries. The procedure will be conducted on consenting patients diagnosed with a CTO in a coronary vessel that requires revascularization after a previously failed attempt to cross or refractory to 10 minutes of conventional guidewire attempt.

Study objective

The purpose of this trial is to evaluate the safety and effectiveness of the NovaCross* micro-catheter when used to facilitate crossing of Chronic Total Occlusion (CTO) lesions in coronary arteries. The procedure will be conducted on consenting patients diagnosed with a CTO in a coronary vessel that requires revascularization after a previously failed attempt to cross or refractory to 10 minutes of conventional guidewire attempt.

Study design

This is a prospective, non-randomized, multi-center, pivotal investigational study, intended to assess the safety and effectiveness, and deployment and withdrawal characteristics of the NovaCross* micro-catheter during interventional coronary angioplasty procedures involving efforts to cross previously refractory CTOs.
Each study subject/patient will have a total of one (1) NovaCross* procedure performed for this study.
All Data will be collected at baseline, procedure, and 30 days post procedure.
All adverse events will be recorded, and serious adverse events will be reported in accordance with EC and regulatory requirements.

Intervention

The anterograde approach is the first choice technique in the vast majority of percutaneous interventions of CTOs. After choosing the adequate guiding catheter for maximal back-up support, and ensuring good distal vessel opacification either by ipsilateral circulation or simultaneous contralateral injection, it is mandatory to select the angiographic projection that best shows the characteristics of the entrance to the CTO. To monitor the progression of the guide wire over the microcatheter, an orthogonal view should be selected and mentally trace the pathway to be followed by the guide wire from the proximal cap to the distal lumen through the entire occlusion.

Selection of a Guide wire
Guide wire for a true CTO should be selected according to the age and morphological features of the occlusion. Although there is a great variability in guide wire selection to start a CTO procedure among experienced operators, some general recommendations can be made:
* In a true CTO it is unlikely that floppy wires will cross the occlusion.
* Stiff wires should not be advanced through the proximal segment of a CTO, especially when some tortuosity is present, due to the risk of damaging the arterial
wall. A floppy wire is the best choice to negotiate the proximal segment to the CTO and advance an OTW catheter up to the proximal stump and then exchange to a dedicated stiffer wire.
* Polymeric coated guide wires may be the first choice when intraluminal microchannels are visible on angiography, and in some angulated and calcified lesions. Because of the poor tactile feedback of these wires, careful attention should be paid to avoid the creation of long subintimal dissections.
* The majority of operators will choose a hydrophobic spring coil dedicated guide wire for a CTO to start the procedure, with a step-up approach with wires of moderate stiffness at the beginning with a subsequent switch to wires of greater tip load for penetration capacity. Others believe that the risk of dissections can be reduced and the procedure shortened by selecting stiffer

wires in the first place.
* Operators should be familiar and use a limited set of or dedicated CTO guide wires.
* The wires should be used in combination with a microcatheter *NovaCross* micro catheter to assist in preventing flexion and prolapsing of the wire transmitting the push directly to the tip, facilitating torque transmission and allowing wire exchange, which is frequently needed during a CTO procedure.

During the Procedure:
Unless previously failed CTO crossing attempt was documented, the operator should attempt to cross the CTO with guidewire for 10 minutes. Then after, The CTO will be penetrated and crossed using a designated CTO guide wire (A number of dedicated guide wires are available for CTO crossing. Individual operators will select a guidewire with crossing characteristics that are likely to be successful for the specific anatomy encountered in the procedure. However, the wires should be used in combination with a NovaCross* micro catheter to assist in preventing flexion and prolapsing of the wire transmitting the push directly to the tip, facilitating torque transmission and allowing wire exchange, which is frequently needed during a CTO procedure.) assisted by the NovaCross* micro catheter. The NovaCross* will be placed/ positioned just proximal to the CTO site (~5-15 mm) to facilitate the guide wire crossing procedural step. The Nitinol loops will be deployed prior and during guide wire penetration and propagation throughout the blocked segment. Following CTO guidewire crossing, angiographic imaging will be obtained, the Nitinol loops will be collapsed and the NovaCross* withdrawn. An Investigator chosen revascularization method should follow.

Review of existing angiographic data of the treated vessel's post CTO crossing should be obtained. Blood workup post procedure will occur at 3-6 hours and then 12±4 hours to measure Troponin and CK-MB along with an ECG to assess for peri-procedural myonecrosis.

The need for epinephrine given during the procedure and signs or symptoms of anaphylaxis will be captured and information relating to the causality will be provided.

Study burden and risks

Risks of PTCA are uncommon, and the procedure is widely practiced. Typical known risks or discomforts anticipated as a result of a PTCA procedure include:
* Recurrence of angina
* Chest discomfort
* Bleeding from catheter the insertion point
* Bruising at the catheter insertion point
* Hematoma at catheter insertion point
* Ischemia due to restenosis of the dilated segment
* Ventricular failure

* Dissection or thrombosis with vessel occlusion
* Arterial Perforation
* Surgery required
* Vessel trauma
* Blood Toxicity
* Infection
* Toxicological response
* Fever
i. Rare risks as a result of a PTCA procedure
* Infection at skin puncture site
* Allergic reaction to contrast dye
* Deterioration of kidney function/kidney failure
* Provocation of heart attack/stroke
* Surgery to recover failed devices
* Surgery to repair a failed procedure
* Prolonged procedure time
* Occlusion of a branch of coronary artery
* Myocardial infarction with release of CK-MK into circulation
* Death
* When failures of PTCA occur, they are often treated using coronary artery bypass surgery

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. Adult aged 25-80
2. Patient understands and has signed the study informed consent form.
3. Patient has an angiographic documented Chronic Total Occlusion (i.e. >3 months occlusion duration) showing distal TIMI flow 0.
4. Suitable candidate for non-emergent, coronary angioplasty
5. Documented coronary angiography preceding the PCI reveals at least one CTO lesion situated in a non-infarct related coronary artery or its side branches with the following characteristics:
a) Thrombolysis in Myocardial Infarction (TIMI) 0 flow for at least 90 days;
b) Satisfactory distal vessel visualization
c) CTO should be amenable to percutaneous treatment and must be located in a coronary vessel with a reference diameter of at least 2 millimeters.
d) CTO refractory to a minimum of 10 minutes of conventional guide wire attempt.
6. Body Mass Index (BMI) < 40
7. Left ventricle ejection fraction > 25%
For the purpose of this trial, a CTO is defined as a 100% luminal narrowing without antegrade flow or

Exclusion criteria

1. Patient unable to give informed consent.
2. Current participation in another study with any investigational drug or device.
3. Patient is known or suspected not to tolerate the contrast agent.
4. Aorto-ostial CTO location (Ostial bifurcation origins may be considered), SVG CTO, in-stent CTO.
5. Intolerance to Aspirin and/or inability to tolerate a second antiplatelet agent (Clopidogrel and Prasugrel and Ticagrelor).
6. Appearance of a fresh thrombus or intraluminal filling defects.
7. Recent major cerebrovascular event (history of stroke or TIA within 1 month)
8. Cardiac intervention within 4 weeks of the procedure
9. Renal insufficiency (serum creatinine of > 2.3mg/dl or 203umol/L)
10. Active gastrointestinal bleeding
11. Active infection or fever that may be due to infection
12. Life expectancy < 2 years due to other illnesses
13. Significant anemia (hemoglobin < 8.0 mg / dl)

14. Severe uncontrolled systemic hypertension (> 240 mmHg within 1 month of procedure)
15. Severe electrolyte imbalance
16. Congestive heart failure [New York Heart Association (NYHA) Class III\IV] CSA Class IV.
17. Unstable angina requiring emergent percutaneous trans-luminal coronary angioplasty (PTCA) or coronary artery bypass graft (CABG)
18. Recent myocardial infarction (MI) (within the past two weeks)
19. Uncontrolled diabetes >2 serum glucose concentrations of >350 mg/dl within 7 days.
20. Unwillingness or inability to comply with any protocol requirements
21. Pregnant or nursing
22. Extensive prior dissection from a coronary guidewire use
23. Drug abuse or alcoholism.
24. Patients under custodial care.
25. Bleeding diathesis or coagulation disorder;
26. Kawasaki's disease or other vasculitis.

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-11-2015
Enrollment:	50
Type:	Actual

Medical products/devices used

Generic name:	NovaCross chronic total occlusion micro-catheter
Registration:	No

Ethics review

Approved WMO Date:	05-08-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-10-2015
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
CCMO	NL51902.029.14