Clinical investigation of the Qmedics EXIST NiTi Stent type Flex & Pull in adults with Peripheral Artery Disease (PAD) (of the Q-medics NiTi Stent Family.

Published: 30-05-2023
Last updated: 05-04-2024

The objective of the HORIZON trial is to demonstrate and provide long-term clinical data on safety and performance of the Qmedics EXIST NiTi Stent System type FLEX & PULL for treating de novo or re-stenotic symptomatic atherosclerotic lesions in...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Arteriosclerosis, stenosis, vascular insufficiency and necrosis
Study type	Observational non invasive

Summary

ID

NL-OMON52001

Source
ToetsingOnline

Brief title
HORIZON

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
Peripheral Artery Disease;

Research involving
Human

Sponsors and support

Primary sponsor: QMedics AG

Source(s) of monetary or material Support: QMEDICS

Intervention

Keyword: Peripheral Artery Disease, Stents

Outcome measures

Primary outcome

The primary and secondary endpoints and additional endpoints will be evaluated

on an intent-to-treat

analysis and a per-treatment analysis. If a subject is enrolled, but a Qmedics

EXIST NiTi Stent type FLEX

or PULL is not implanted, the subject will not be followed through the

follow-up visits.

8.1 Primary Performance Endpoint

The primary patency rate is determined as primary performance endpoint (defined

as freedom from

more than >= 50% restenosis) at 6 - 12 months post-index procedure as measured

by PSVr at duplex

ultrasound (DUS). Peak systolic velocity ratio (PSVr) is calculated as peak

systolic velocity within the

area of the stenosis divided by peak systolic velocity in a normal adjacent

proximal artery segment. A

PSVr * 2,5 suggests a reduction in the luminal diameter >50%.

The primary safety endpoint is defined as the freedom from procedure- or

stent-related Major Adverse

Events (MAE*s) at 30-days post index-procedure. MAE is defined as all causes of

death and target limb

major amputation.

Secondary outcome

For the secondary endpoint following data will be collected:

Clinical success

1. Defined as improvement of Rutherford and Fontaine classification at 6- and

12-months follow-up of one class or more as compared to the pre-procedure and

an ankle-brachial index

improvement (ABI) by >= 0.15

Technical Succes:

2. To demonstrate that the Qmedics NiTi stent improves the primary patency with

>50% of

subjects with peripheral artery disease compared with literature data.

3. Stent fracture rate at 12- and 24-month follow-up. Evaluation at 12 and 24

months with x-ray.

Stent fracture is defined according to the following classification on x-ray:

Type 0: no structural fractures

Type I: single tine fracture

Type II: multiple tine fractures

Type III: stent fracture(s) with preserved alignment of the components

Type IV: stent fracture(s) with mal-alignment of the components

Type V: stent fracture(s) in a trans-axial spiral configurationHORIZON

Confidential

3. Walking Improvement at 30 days, 6, 12 and 24 months assessed by change in

Walking

Impairment Questionnaire (WIQ) from baseline

4. Measurement of the freedom of Target Lesion Revascularization (fTLR)

5. Patency rate and MAE at 24 months

Study description

Background summary

Large set of investigations have been conducted that demonstrating safety and effectiveness for
devices from which components have been leveraged for the Qmedics NiTi Stent System family.
Successful results have been seen so far demonstrate safety and effectiveness for a variety of
indications in peripheral artery stenosis.
The overall rationale for this investigation is to provide long term clinical data on safety and
performance of the Qmedics EXIST NiTi Stent System type Flex & Pull

Study objective

The objective of the HORIZON trial is to demonstrate and provide long-term clinical data on safety and
performance of the Qmedics EXIST NiTi Stent System type FLEX & PULL for treating de novo or re-stenotic symptomatic atherosclerotic lesions in Peripheral Artery Disease (PAD) requiring treatment of the SFA or P1 segment, and collect additional data including health economics data.

Study design

The HORIZON trial is a prospective, non-randomized, multi-center, multi-national, clinical trial
conducted in several investigational sites in Europe.

Intervention

Placing of stent in periferal artery

Study burden and risks

Considering the nature and objective of the trial, being a Post-Market Clinical Follow-up study with the
primary intention to collect additional data regarding the use of the Qmedics Stent system type FLEX
& PULL, according to standard of care. The additional risk associated with participating in this trial, is
related to the collection of patient data and confidentiality thereof.
The risks associated with the implantation of the Qmedics stent are described in the current applicable
version of the IFU of the Qmedics stent system.
There may be additional risks linked to the procedure, and follow-up testing which are unforeseen at
this time. All assessments planned for the follow-up period are standard of care, apart from the quality
of life- and Walking Impairment questionnaires (QoL and WIQ), which do not cause any additional risk

Contacts

Public
QMedics AG

Winterthurerstrasse 1
Flurlingen 8247
CH
Scientific
QMedics AG

Winterthurerstrasse 1
Flurlingen 8247
CH

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Clinical:
1. Patient age 18 years or older
2. Subject is willing and able to provide consent before any study specific test or procedure is performed, signs the consent form, and agrees to attend all required follow-up visits
3. Symptoms of peripheral arterial disease classified as Rutherford Category 2, 3 or 4 or Fontaine Class IIb or III
4. The stenotic or occlusive lesion in SFA and P1 is considered suitable for stenting
5. No underlying medical condition is present which would prevent the subject from performing the required testing or from completing the study.
6. stable medical condition
Anatomical criteria:
7. Included TASC II, A-B-C measured on pre- angio CT-scan (if CT-scan is standard of care)
8. Lesions must be one or multiple that can be treated with maximum two stents, maximum one overlapping and maximum length of the stent 25 cm *
9. Patent ipsilateral iliac, popliteal (P2 and P3) and at least one tibial vessel

Exclusion criteria

Subjects are excluded if ANY of the following criteria are met:
Clinical criteria:
1. Subjects pregnant, breastfeeding or planning to become pregnant during the trial participation
2. Documented life expectancy less than 24 months due to other medical co-morbid condition(s)
3. Thrombophlebitis or deep vein thrombosis within the past 30 days.
4. Impossibility in assuming DAPT
5. Concomitant renal failure with serum creatinine level > 2.5 mg/dL (or > 220 *mol/L) or

GFR < 30 ml/min/1,73 m2HORIZON Confidential
QME_HORIZON_CIP v1.0_01-oct-2019 page 15 of 52
6. Unresolved neutropenia (white blood cell count < 3,000 / µL) or thrombocytopenia (platelet
count < 80,000 / µL) at the time of the index procedure
7. Unresolved bleeding disorder (INR >= 1.2) at the time of the index procedure
8. Active gastrointestinal bleeding
9. Anticoagulation therapy for other medical condition
Anatomical criteria:
10. Target lesion(s) received previous treatment within 30 days prior to enrolment (point of
enrolment is defined as the time when the trial device enters the body)
11. Previously stented ipsilateral SFA
12. Prior peripheral vascular bypass surgery involving the target limb(s)
13. Target lesion is located within an aneurysm or associated with an aneurysm in the vessel
segment either proximal or distal to the target lesion
14. Target lesion requires the use of cutting balloons, atherectomy or DCB during the intervention

Study design

Design

Study phase:	4
Study type:	Observational non invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	50
Type:	Anticipated

Medical products/devices used

Generic name:	Qmedics Exist NiTi stent

Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	30-05-2023
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NCT05234164
CCMO	NL78634.078.21