The IN.PACT Global Clinical Study for the Treatment of Comprehensive Superficial Femoral and/or Popliteal Artery Lesions Using the IN.PACT Admiral* Drug-Eluting Balloon

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To prospectively collect and assess global safety and efficacy data on the IN.PACT Admiral* Drug Eluting Balloon (DEB) in treatment of atherosclerotic disease of the superficial femoral and/or popliteal arteries in *real world* patient population.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Vascular therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON41409

Source
ToetsingOnline

Brief title
IN.PACT Global Clinical Study

Condition

- Vascular therapeutic procedures
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
Arteriosclerosis and occlusion of the SFA and the PA

Research involving
Human

Sponsors and support

Primary sponsor: Medtronic B.V.
Source(s) of monetary or material Support: Door de sponsor van het onderzoek

Intervention

Keyword: Drug Eluting Balloon, IN.PACT Admiral, PA, SFA

Outcome measures

Primary outcome

A composite of freedom from device- and procedure-related mortality through 30 days, freedom from major target limb amputation and TLR within 12 months post-index procedure.

Secondary outcome

Clinical Cohort:

1. MAEas at 30 days, 6, 12, 24, 36, 48 and 60 months.

a MAE is defined as all-cause mortality, clinically-driven TVR, major target limb amputation, thrombosis at the target lesion site.

2. All-cause mortality at 30 days, 6, 12, 24, 36, 48 and 60 months.

3. Clinically-driven TLR at 30 days, 6, 24, 36, 48 and 60 months.

4. Clinically-driven TVRb at 30 days, 6, 12, 24, 36, 48 and 60 months.

b Clinically-driven TVR is defined as any re-intervention within the target vessel due to symptoms or drop of ABI of >= 20% or > 0.15 when compared to post-index procedure baseline ABI.

5. TLR at 6, 12, 24, 36, 48 and 60 months.

6. TVR at 6, 12, 24, 36, 48 and 60 months.

7. Major target limb amputation at 30 days, 6, 12, 24, 36, 48 and 60

months.

8. Time to first clinically-driven TLR through 60 months post-index procedure.

9. Time to all-cause mortality through 60 months post-index procedure.

10. Primary sustained clinical improvementc at 6, 12, 24, 36 months.

c Primary sustained clinical improvement is defined as sustained upward shift of at least 1 category on Rutherford classification as compared to baseline without the need for repeated TLR or surgical revascularization in amputation-free surviving subjects.

11. Secondary sustained clinical improvementd at 6, 12, 24, 36 months.

d Secondary sustained clinical improvement is defined as sustained upward shift of at least 1 category on Rutherford classification as compared to baseline including the need for repeated TLR or surgical revascularization in amputation-free surviving subjects.

12. Immediate hemodynamic improvemente at post-index procedure.

e Immediate hemodynamic improvement is defined as an ABI improvement of >= 0.1 or to an ABI >= 0.9.

13. Sustained hemodynamic improvementf at 6, 12, 24, 36 months.

f Sustained hemodynamic improvement is defined as persistent improvement of ABI-values with >= 0.1 as compared to baseline values or to an ABI >= 0.9 throughout follow-up without the need for repeated TLR or surgical revascularization in amputation-free surviving subjects.

14. Walking impairment evaluation by Walking Impairment Questionnaire (WIQ) at 6, 12, 24, 36 months.

15. Walking distance as measured by 6 Minute Walk Test at 6, 12, 24, 36 months.

16. Health related Quality of life scores (EQ5D) at 6, 12, 24, 36 months.

17. Device successg

g Device success is defined as successful delivery, balloon inflation and deflation and retrieval of the intact study device without burst below the rated burst pressure (RBP).

18. Procedural successh

h Procedural success is defined as residual stenosis of <= 50% (non-stented subjects) or <= 30% (stented subjects) by visual estimate.

19. Clinical successi

i Clinical success is defined as procedural success without procedural complications (mortality, major target limb amputation, thrombosis of the target lesion, or TVR) prior to discharge.

Imaging Cohort:

20. Duplex-defined binary restenosis (PSVR > 2.0) of the target lesion at 12 months, or at the time of re-intervention.

21. Duplex-defined binary restenosis (PSVR > 3.4) of the target lesion at 12 months, or at the time of re-intervention.

Study description

Background summary

Peripheral artery disease (PAD) commonly results from progressive narrowing of the arteries

in the lower extremities, usually due to atherosclerosis. In claudicant subjects approximately 30% of the lesions are located in the iliac arteries and 70% in the femoro-popliteal and tibial tract; a small percentage is located in the vasculature below the knee. Risk factors for development of PAD include diabetes, smoking, hypertension, dyslipidemia, increasing age and chronic renal insufficiency. Individuals with PAD often experience intermittent claudication, although some may be asymptomatic. Progression of PAD can result in critical limb ischemia (CLI), manifested by ischemic pain at rest or in the breakdown of the skin, resulting in ulcers or gangrene which ultimately may lead to amputation and death.

The prevalence of PAD has been evaluated in several epidemiologic studies and is estimated to be in the range of 5% to 30% in adult population in industrialized countries. Data from the 1999-2000 National Health and Nutrition Examination Survey in the US revealed that PAD, defined as ABI < 0.9 in either leg, was 4.3% in adults aged 40 years and over. This means that about 5 million individuals are expected to have PAD. Among those aged 70 years or over, the prevalence was 14.5%. Other studies confirmed that the prevalence of PAD, using similar diagnostic criteria, ranged from 3% to 4% among middle-aged adults and between 13% and 14% in the elderly. The incidence and prevalence of PAD increases substantially with age in both males and females.

Study objective

To prospectively collect and assess global safety and efficacy data on the IN.PACT Admiral* Drug Eluting Balloon (DEB) in treatment of atherosclerotic disease of the superficial femoral and/or popliteal arteries in *real world* patient population.

Study design

Prospective, multi-centre, single-arm study.

Intervention

All patients are treated with the IN.PACT Admiral* Drug Eluting Balloon (DEB)manufactured by Medtronic. The IN.PACT Admiral* is a CE marked medical device utilized within its intended use in the IN.PACT Global trial.

Study burden and risks

Based on our current knowledge, participation into the IN.PACT Global Clinical Study
does not impose additional risks. There is a high probability that subjects benefit when using a
DEB as several studies have shown clinical and angiographical superiority when compared to
standard PTA. The potential benefits of the study outweigh the potential risks; therefore the
investigation is justified. It is possible in any clinical trial that harmful things can happen which
are not known at this time. All efforts will be made to minimize the risks in this study by
selecting investigators who are experienced and trained in the use of the study device and
trained to the study protocol, by clearly defining inclusion/exclusion criteria to ensure only
appropriate subjects are enrolled, and by ensuring that treatment and follow-up of the subject
are consistent with current medical practices.
Due to the low dosage and local administration of paclitaxel, drug reactions have not been
reported and are not to be expected.

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

* Age >= 18 years or minimum age as required by local regulations.
* Subject with documented diagnosis of peripheral arterial disease (PAD) in the superficial femoral artery (SFA) and/or popliteal artery (PA) (including P1, P2, P3) classified as Rutherford class 2-3-4.
* Angiographically documented single or multiple lesions/occlusions (de novo or re-stenotic lesion(s) or in-stent restenosis) within the target vessels with a minimum lesion length of 2 cm including bilateral disease if both limbs are treated within 35 days.
* Positive diagnostic indication for PTA with a DEB in accordance with the Instructions For Use (IFU) of the IN.PACT Admiral* DEB.
* Adequate distal run-off to the ankle (at least one native calf vessel [posterior tibial, anterior tibial, or peroneal arteries] is patent, defined as <= 50% diameter stenosis) either pre-existing or successfully reestablished prior to target lesion treatment.
* Adequate inflow (<= 50% diameter stenosis) either pre-existing or successfully re-established prior to target lesion treatment.
* Female subjects of childbearing potential must have a negative pregnancy test <= 7 days before enrollment.
* Signed and dated Patient Informed Consent (PIC) form.
* Ability and willingness to comply with the clinical investigation plan (CIP).
* Life expectancy, in the Investigator*s opinion, of at least 12 months.

Exclusion criteria

* High probability of non-adherence to CIP follow-up requirements.
* Failure to successfully cross the target lesion with a guide wire (successful crossing means tip of the guide wire distal to the target lesion

in the absence of flow limiting dissections or perforations).
* Lesion within or adjacent to an aneurysm or presence of a popliteal aneurysm.
* Acute or sub-acute thrombus in the target vessel.
* Previous bypass surgery to the target lesion.
* Target lesion also requires treatment with alternative therapy such as drug-eluting stent (DES), laser, atherectomy, cryoplasty, cutting/scoring balloon, brachytherapy.
* Plan for surgical or interventional procedure within 30 days after the study procedure (except for bilateral target limb treatment).
* Known allergies or sensitivities to heparin, aspirin, other anticoagulant/ anti-platelet therapies, and/or paclitaxel.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-03-2013
Enrollment:	60
Type:	Actual

Medical products/devices used

Generic name:	Paclitaxel drug eluting balloon (hereinafter referred as □IN.PACT Admiral□ DEB□) manufactured by Med
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	04-12-2012
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	20-12-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	22-04-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	19-05-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	30-11-2015
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
ClinicalTrials.gov	NCT01609296
CCMO	NL40343.100.12