Randomized Study of IN.PACT Amphirion* Drug Eluting Balloon (DEB) vs. standard PTA for the treatment of below the knee critical limb ischemia [IN.PACT DEEP]

Published: 14-07-2011
Last updated: 28-04-2024

1. Evaluate safety and clinical and angiographic efficacy of BTK revascularization with IN.PACT Amphirion* randomized to standard, uncoated PTA balloons2. Assess the clinical efficacy of BTK revascularization with IN.PACT Amphirion* compared to a...

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

Summary

ID

NL-OMON39405

Source
ToetsingOnline

Brief title
INPACT DEEP
Treat critical ischemia btk with Drug Eluting Balloon

Condition

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

Synonym
Ischemia. Narrowing or obstructions of arteries below the knee

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: below the knee, IN.PACT Amphirion DEB, Ischemia, Randomized

Outcome measures

Primary outcome

1. For the Angio-cohort: late lumen loss (LLL) of the target lesion as assessed

by quantitative vascular angiography (QVA) either at 12 months or at a time of

a Target Lesion Revascularization (TLR).

2. For all patients: cumulative *clinically driven* TLR of the target lesion in

the (major) amputation free surviving patients at 12 months.

Clinically driven TLR is defined as any TLR of the target lesion associated

with:

a. Deterioration of Rutherford Class and / or

b. Increase in size of pre-existing wounds and / or

c. Occurrence of a new wound(s)

with options b. and c. as adjudicated by the wound healing core lab.

3. Composite of all cause death, major amputation and clinically driven TLR at

6 months

Secondary outcome

1. Amputation free survival at 30 days, 3 and 6 months, 1, 2, 3, 4 and 5 years

2. Rate of wound healing at 30 days, 6 months, 1 and 2 years

3. Amputation free survival and wound healing at 6 months, 1 and 2 years

4. Amputation free survival and resolved CLI at 6 months, 1 and 2 years

5. Death, amputation and clinically driven TLR at 30 days, 6 months, 1 and 2 years

6. Primary sustained clinical improvement: an improvement shift in the Rutherford classification of one class in amputation free, clinically driven TLR free surviving patients at 1 year

7. Secondary sustained clinical improvement: an improvement shift in the Rutherford classification of one class including the need for clinically driven TLR in amputation free surviving patients at 1 year

8. Quality of life assessment by EQ5D (EuroQol 5 Dimensions) at 6 months, 1, and 2 years vs. baseline

9. Walking capacity assessment by WIQ at 6 months, 1, and 2 years

10. MAE (Major Adverse Events) at 30 days, 6 months, 1, 2, 3, 4, 5 years (for definition refer to section 14 Terms & Definitons)

11. Device Success defined as exact deployment of the device according to the instructions for use as documented with suitable imaging modalities and in case of digital subtraction angiography, in at least 2 different imaging projections

12. Technical Success defined as successful vascular access and completion of the endovascular procedure and immediate morphological success with <= 50% residual diameter reduction of the treated lesion on completion angiography

13. Procedural Success defined as combination of technical success, device success and absence of procedural complications

14. For the Angio-cohort: improvement in 12 month % diameter stenosis (%DS) of

the TL assessed by Quantitative Vascular Angiography (QVA)

15. Days of hospitalization

Study description

Background summary

The social and economic burden of CLI is enormous and its growth on a global basis, remain unceasing. It is estimated that between 220,000 to 240,000 major and minor lower extremity amputations are performed in the United States and Europe yearly due to CLI. Historically, the gold standard for treatment of CLI has been surgical revascularization. However, this approach is limited to subjects with good distal target vessels and lack of severe comorbid condition as advanced age and several co-morbidities, such as diabetes and coronary artery disease, have shown to increase the surgical risk. Objective advantages of PTA vs surgery are related to a lower procedural morbidity and mortality, reduced costs, faster procedural time and shorter hospital stay. Several pre-clinical and clinical trials, both in coronary and peripheral indications, have already been published showing safety and efficacy of paclitaxel eluting balloon catheters.

Study objective

1. Evaluate safety and clinical and angiographic efficacy of BTK revascularization with IN.PACT Amphirion* randomized to standard, uncoated PTA balloons
2. Assess the clinical efficacy of BTK revascularization with IN.PACT Amphirion* compared to a Performance Goal (PG) of 12 month Amputation Free Survival (AFS) derived from the surgical literature.

Study design

Prospective, multi-center, randomized (2:1) study of BTK balloon angioplasty with the IN.PACT Amphirion* vs standard non-coated balloons (control arm). Following a double randomization scheme (see page 20), patients will be assigned to either angiographic follow up (Angio-cohort) and clinical follow up or sole clinical follow up, based on the target lesion presentation

Intervention

BTK revascularization with IN.PACT Amphirion* randomized to standard, uncoated PTA balloons

Study burden and risks

There is no or only a minimal additional burden as this patient population (CLI patients) needs to return to the hospital quite frequently. Even if some patients are required to undergo a re-angio at 1 year it is expected that a lot of patients need to come back for a re-PTA even earlier (primary patency at 1 year in this patient population is approx. 50%)

Contacts

Public
Medtronic B.V.

Endepolsdomein 5
Maastricht 6229GW
NL
Scientific
Medtronic B.V.

Endepolsdomein 5
Maastricht 6229GW
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

-Patient has documented chronic Critical Limb Ischemia (CLI) in the target limb prior to the study procedure with Rutherford Category 4, 5 or 6

-Life expectancy >1 year in the Investigator*s opinion
-Reference vessel(s) diameter between 2 and 4 mm
-Single or multiple lesions with >=70% DS of different lengths in one or more main afferent crural vessels including the tibioperoneal trunk
-Angio-TL is one identifiable single solitary or series of multiple adjacent lesions with a DS >=70% and a cumulative length <=100 mm that can be covered by a single IN.PACT Amphirion* (10 mm balloon landing zone in both edges is mandatory)

Exclusion criteria

-Planned major index limb amputation
-Lesion and / or occlusions located or extending in the popliteal artery or below the ankle joint space
-Inflow lesion or occlusion in the ipsilateral Iliac, SFA, popliteal arteries with length >=15 cm
-Significant (>=50% DS) inflow lesion or occlusion in the ipsilateral Iliac, SFA and popliteal arteries left untreated
-Previously implanted stent in the TL(s)
-Aneurysm in the target vessel
-Acute thrombus in the target limb
-Failure to obtain a <30% residual stenosis in pre-existing, hemodynamically significant (>=50% DS and <15 cm length) inflow lesions in the ipsilateral iliac, SFA and popliteal artery. No Drug Eluting Stents (DES) and / or DEB allowed for the treatment of inflow lesions

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:	Recruitment stopped
Start date (anticipated):	30-01-2012

Enrollment:	80
Type:	Actual

Medical products/devices used

Generic name:	Paclitaxel drug eluting balloon catheter
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	14-07-2011
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	06-02-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	05-06-2013
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
Other	http://clinicaltrials.gov/ct2/results?term=IN.PACT+DEEP
CCMO	NL36046.100.11

Study results

Date completed:	01-07-2013
Actual enrolment:	2