BIBLIOS STUDY

Belgium-Italian prospective, single-arm, multicentre study to evaluate the efficacy and safety of BTK treatment with Luminor-14 Pacltaxel coated Percutaneous Transluminal Angioplasty Balloon catheter of I-Vascular

Of 150 Subjects with Critical Limb Ischemia

PI: K. Deloose
Biblios Study

Objective:
Clinical investigation to access the safety and efficacy of the Luminor-14 DCB for the treatment of infrapopliteal lesions in 150 subjects with critical limb ischemia
Luminor-14m Paclitaxel coated DCB

- Durable Coating to minimize drug loss
- Outstanding size range 0.014”- 0.018”- 0.035” GW compatibility
- Best DCB in SFA results
  98.7% freedom of TLR and 90.4% PP
- Transfertech: nanotechnology for uniform and ultrathin layer Paclitaxel
Coating process

Ultrasound
Spray Technology
Dosage of uniform diameter nanodrops by ultrasonic deposition

Excipient 20%
Paclitaxel 80%
Excipient
- Organic ester
- Biocompatible
- Lipophilic
Paclitaxel
- Lipophilic
- Inhibition of stenosis
- Specific cellular receptors

Uniform coating
Homogeneous drug dose

Multi-layer technology
- Coating durability during the procedure
- No cracking

TransferTech
Dry-off
- Microcrystalline structure
- Optimal drug transfer to the vessel wall within 30-60s seconds

Nanotecnología propia para un recubrimiento durable, fino y homogéneo
Technological features

Dosage of uniform diameter nanodrops by direct spray ultrasonic deposition

• Ultrathin multilayer coating:
  • Increases adhesion to balloon
  • Lower loss related to manipulation
  • Improves durability:
    • Lower loss during navigation
    • Improves coating flexibility

• Homogeneous distribution of drug
  • Same dose along the entire length

• Excellent drug Transfer
  • Fast absorption 30-60 sec

SEM: magnify: x 1000

Crystalline Paclitaxel
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Primary Endpoints:

1 Efficacy endpoint @ 6 month: Freedom from Male

Freedom from major adverse limb events (MALE) at 6 month defined as absence of above-ankle target limb amputation or major re-intervention to the target lesion(s) (i.e. new bypass, trombectomy, thrombolysis)

2 Safety endpoint @ 30 days:

Freedom from Male or POD

Peri-operative death (POD) at days, device or procedure related or any other cause
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Secondary Endpoints

1 Target vessel functional Flow Assessment @ 6 and 12 months

defined as the presence of bloodflow using duplex. If angiography is available within the 12 month visit it should be used instead of duplex.

2 Freedom from CD-TLR @ 6 and 12 months

defined as absence of any reintervention due to clinical deterioration, defined as:
- worsening of the patient’s quality of life (EQ5D-questionnaire)
- worsening of Rutherford category with minimal 1 class
- worsening of wound status
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Secondary Endpoints

3 Amputation free survival @ 6 and 12 months
defined as alive with freedom from any above-the-ankle target limb amputation

4 Limb salvage @ 6 and 12 months
defined as freedom from any above-the-ankle target limb amputation at 6 and 12 months
5 Procedural success

defined as restoration of at least 1 below-the-knee (BTK) artery within <30 % residual stenosis in the final angiogram and outflow to the foot

6 Wound healing status

based on three parameters: the wound’s diameter, the wound’s depth and the % granulation tissue

7 Wound healing time !!!

defined as the number of days needed for the wound to heal completely after the index procedure
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Inclusion criteria

- Rutherford Classification 5
- Significant degree of stenosis >70% or chronic total occlusion (CTO)
- P3 to the ankle-joint level (not below the ankle)
- Wifi tissue loss grade 1-2 at baseline
- Wifi foot infection grade 0-2 at baseline
- Wifi ischemia grade 2-3 at baseline
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Inclusion criteria

- Target vessel should give direct or indirect run-off to the foot
- Successful predilatation of the target lesion (<30% residual stenosis)
- In-flow lesions can be included if lesions are treated successfully (residual stenosis<30%) with same DCB platform and bail-out stenting with BMS
General inclusion

**Tissue Loss**
- 0: No ulcer and no gangrene
- 1: small ulcer and no gangrene
- 2: deep ulcer or gangrene limited to toes
- 3: extensive ulcer or extensive gangrene

**Ischemia**
- Toe pressure (TP)
  - 0: > 60 mmHg
  - 1: 40-59 mmHg
  - 2: 30-39 mmHg
  - 3: < 30 mmHg
- Transcutaneous oximetry (TcPO²)
  - 0: > 60 mmHg
  - 1: 40-59 mmHg
  - 2: 30-39 mmHg
  - 3: < 30 mmHg

**Infection**
- 0: no symptoms or signs of infection
- 1: mild (< 2cm cellulitis)
- 2: moderate (> 2cm cellulitis/purulence)
- 3: severe (systemic response/sepsis)
Procedure (before treating target lesion)

- Contralateral treatment; allowed
- Inflow lesion treatment: allowed
- Endovascular or surgical procedure 30 days after procedure in target limb: not allowed
- Vascular access: site standard of care
- Inflow limiting lesion (>50% stenosis)
  - Must be treated successfully (<30% stenosis)
  - Standard of care (if DCB: only Luminor)
- If multiple BTK arteries → 1 study lesion!
  - Non-target lesions: per standard of care (no drug eluting technologies)
Procedure overview

Successful inflow:
- Treatment
  - Successful crossing with guidewire:
    - YES
    - NO
      - Screen Failure
    - NO
  - NO
  - NO
  - NO
  - NO
  - NO
  - NO
  - NO

Successful pre-dilatation:
- Successful dilatation:
  - YES
  - NO
  - NO
  - Screen Failure
Successful dilatation

NO
>30 RS

Succesful Prolonged dilation

NO

BMS bail-out stenting

Procedure Success

YES

DCB Balloon = longer than lesion 5mm healthy vessel
If more DCB’s overlap mandatory = overlap of 1cm
Biblos study
Luminor 14 Paclitaxel coated in BTK vessel i-vascular

- Start inclusions january 2019
- Hope to End inclusions january 2020
- Hope to Report results january 2021
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