

# STAR-PAK Study: Evaluating the Safety and Efficacy of PAK® (Paclitaxel Coated Balloon) in Treating Atherosclerotic Femoro-Popliteal Lesions

NCT06734221

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Status	RECRUITING
Phase	Not Applicable
Sponsor	Balton Sp.zo.o.
Enrollment	120 participants

## Key Eligibility Criteria

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### Inclusion (11)

- Age e 18 years.
  - Written informed consent of the patient to participate in the study.
  - Symptoms of lower limb ischemia defined by Rutherford classification from 2 to 4.
  - At least one de novo or restenotic lesion, in SFA and/or PA defined as a lesion with a proximal origin  $\geq 10$ mm from SFA origin and a distal end above the knee joint (at least 3 cm above bottom of the femur- P1).
  - Target Lesion  $\geq 60\%$  stenosis in the SFA or PA (based on angio-CT and/or confirmed in angiography).
- ... and 6 more (see full listing online)

### Exclusion (19)

- Life expectancy less than 2 years.
  - Suspected or detected malignancy without completed treatment (not considered cured).
  - Planned surgical or interventional procedures within 30 days after the study procedure.
  - Known impaired renal function with GFR  $\leq 30$  mL/min per  $1.73$  m<sup>2</sup> and/or elevated serum creatinine  $\geq 2.5$ mg/dL or on dialysis.
  - Active inflammatory process at the site of the planned puncture.
- ... and 14 more (see full listing online)

## Locations (3 total)

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Department of Vascular Surgery; Malopolska Cardiovascular Center; Polish-American Heart Clinics, Chrzanów, Malopolska, Poland

University Hospital Clinical Hospital No. 2 PUM in Szczecin, Department of General, Dental and Interventional Radiology, Szczecin, West Pomeranian Voivodeship, Poland

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