

Use of Shockwave M5+/L6 IVL Catheter (Intravascular Lithotripsy) in Hostile and Calcified Iliac Access

NCT05880641

Status RECRUITING
Sponsor EndoCore Lab s.r.l.
Enrollment 40 participants

Key Eligibility Criteria

Inclusion (9)

- Age ≥18 years old;
 - Patient (or their legal representative) understands the nature of the procedure and provides written informed consent, prior to enrolment in the study;
 - Patient presenting with aortic disease indicated for endovascular treatment considered unfeasible based on severely calcified iliac access and outer diameter of the "ideal" aortic endograft at onset of the procedure (considering the main body and/or contralateral limb in case of iliac distal landing zone);
 - Patients presenting a ratio > 0.2 between outer diameter of the aortic stent graft delivery system (OD-SG) and minimum lumen diameter (MLD); decision concerning SG will be taken balancing the lower profile on the market and the better graft fit for patient's anatomy;
 - Patients presenting calcium grade 3 or 4 accordingly to 360° coronary classification (grade 1 = 0-90°, grade 2 = 90°-180°; grade 3 = 180°-270°; grade 4 = 270°-360°);
- ... and 4 more (see full listing online)

Exclusion (7)

- Bilateral Iliac Occlusion;
 - Urgent setting with presence of iliac thrombus (acute limb ischemia);
 - Any patient considered to be hemodynamically unstable at procedure onset;
 - Patients refusing treatment;
 - Patients for whom antiplatelet therapy, anticoagulants or thrombolytic drugs are contraindicated;
- ... and 2 more (see full listing online)

Locations (6 total)

Azienda Ospedaliero Universitaria delle Marche, Ancona, Ancona, Italy
Sant'Orsola Hospital, Bologna, Emilia-Romagna, Italy
Fondazione PTV - Policlinico Tor Vergata, Rome, Lazio, Italy
... and 3 more locations