CRUSH PAD: Real-world Outcomes Following Use of Shockwave Intravascular Lithotripsy (IVL) Technology in Calcified Common Femoral Lesions

NCT05145478

Status	RECRUITING
Sponsor	Yale University
Enrollment	50 participants

Key Eligibility Criteria

Inclusion (9)

- Subjects presenting with claudication or CLI by Rutherford Clinical Category 2, 3, 4, 5, or 6 of the target limbs
- Subject is a suitable candidate for angiography and endovascular intervention per the latest clinical guidelines
- Patient is scheduled to undergo treatment with Shockwave Intravascular Lithotripsy (IVL) technology followed by standard of care treatment with DCB, BMS, DES at the physician's discretion.
- Target lesion that is located in a native, de novo common femoral artery
- Target lesion reference vessel diameter is between 4.0mm and 7.0mm by visual estimate.

... and 4 more (see full listing online)

Exclusion (8)

- Subjects with any medical condition that would make him/her an inappropriate candidate for treatment with Shockwave Medical Peripheral Lithoplasty® System as per Instructions for Use (IFU) or investigator's opinion.
- Subject is already enrolled in other investigational (interventional) studies that would interfere with study endpoints.
- Cognitive impairment as documented in medical records
- Not speaking English or Spanish
- Currently a prisoner

... and 3 more (see full listing online)

Locations (2 total)

Yale New Haven Health, New Haven, Connecticut, United States
The Miriam Hospital, Providence, Rhode Island, United States