# First In Human Study to Assess Safety and Efficacy of the ChampioNIR™ Drug Eluting Peripheral Stent in the Treatment of Patients With Superficial Femoral Artery Disease and/or Proximal Popliteal Artery Disease

NCT06410313

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| **Status** | RECRUITING |
| **Phase** | Not Applicable |
| **Sponsor** | Medinol Ltd. |
| **Enrollment** | 30 participants |

## Key Eligibility Criteria

### Inclusion (10)

- Age e 18 years and of age of legal consent.
- Subject has lifestyle limiting claudication or rest pain (Rutherford-Becker scale 2-4) with a resting ankle-brachial index/toe-brachial index (ABI/TBI) \<0.90/0.80.
- A single superficial femoral artery lesion with \>50% stenosis or total occlusion.
- Stenotic lesion(s) or occluded length within the same vessel (one long or multiple serial lesions) d 150 mm.
- Reference vessel diameter (RVD) e 3.0 mm and d 5.0 mm by visual assessment.

... and 5 more (see full listing online)

### Exclusion (29)

- Presence of thrombus in the treated vessel as visualized by angiography, prior to crossing the lesion.
- Thrombolysis of the target vessel within 72 hours prior to the index procedure, where complete resolution of the thrombus was not achieved.
- Poor aortoiliac or common femoral "inflow" (i.e. angiographically defined \>50% stenosis of the iliac or common femoral artery) that would be deemed inadequate to support a femoro-popliteal bypass graft and was not successfully treated prior to treatment of the target lesion either within the same procedure or at least 30 days prior to the index procedure.
- Presence of residual e30% stenosis after either PTA or stenting of the inflow lesion.
- Presence of an ipsilateral arterial artificial graft.

... and 24 more (see full listing online)

## Locations (7 total)

Piedmont Healthcare, Inc., Atlanta, Georgia, United States
Columbia University Medical Center/ NewYork Presbyterian Hospital or CUMC/NYPH, New York, New York, United States
St Francis Hospital Heart Center, Roslyn, New York, United States
... and 4 more locations