Self-Expanding Coronary Sinus Reducer for Treatment of Symptomatic Coronary Microvascular Dysfunction (CMD) (SERRA-I Study)

NCT06991322

Status	RECRUITING
Phase	Not Applicable
Sponsor	VahatiCor, Inc.
Enrollment	30 participants

Key Eligibility Criteria

Inclusion (9)

- Older than 18 years of age.
- Left ventricular ejection fraction (LVEF) is greater than or equal to 25% within the 12 months before the index procedure.
- Greater than or equal to 30 days of persistent symptomatic coronary microvascular dysfunction (angina pectoris, or equivalent symptoms) (classified as CCS Grade II-IV angina, or NYHA Class 2 or 3 equivalent non-anginal functional impairment) despite optimal medical therapy as determined by Investigator and confirmed by the Central Screening Committee.
- CFR\<2.5 measured with continuous thermodilution within 30 days of index procedure.
- Sustained angina (or equivalent symptoms) reported for at least 2 weeks leading up to the index procedure, as reported via the ORBITA-app.

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

Exclusion (19)

- Significant obstructive epicardial disease (greater than 50% diameter stenosis) that can be treated with PCI or CABG as determined by Investigator and confirmed by the Central Screening Committee.
- Recent (less than 30 days before index procedure) troponin or CKMB positive acute coronary syndrome (NSTEMI or STEMI) with evidence of ischemia.
- Extra-coronary contributory causes of angina - e.g., untreated hyperthyroidism, anemia (Hgb less than 9 g/dL), uncontrolled hypertension (systolic blood pressure greater than 160 mmHg or diastolic blood pressure greater than 100 mmHg despite medications), atrial fibrillation with a rapid ventricular response (consistently greater than 100 bpm despite medications) or other tachyarrhythmia, severe aortic stenosis, decompensated heart failure, hypertrophic cardiomyopathy with left ventricular outflow tract obstruction or asymmetric septal hypertrophy (concentric left ventricular hypertrophy is not an exclusion criterion).
- NYHA class IV or decompensated HF or hospitalization due to HF during the 90 days before the index procedure.
- Life-threatening rhythm disorders or any rhythm disorders that would require cardiac resynchronization therapy or lead placement in the coronary sinus.

... and 14 more (see full listing online)

Locations (2 total)

University Medical Center Utrecht, Utrecht, Netherlands
Uniwersyteckie Centrum Kliniczne Warszawskiego Uniwersytetu, Warsaw, Poland