Efficacy of the COronary SInus Reducer in Patients With Refractory Angina II

NCT05102019

Status	RECRUITING
Phase	Not Applicable
Sponsor	Shockwave Medical, Inc.
Enrollment	380 participants

Key Eligibility Criteria

Inclusion (17)

- Subject is older than 18 years of age
- Symptomatic coronary artery disease (CAD) with greater than or equal to 90 days of persistent refractory angina pectoris classified as CCS Grade III or IV despite maximally tolerated guideline directed medical therapy as determined by the local heart team and confirmed by a Central Screening Eligibility Committee Note: subjects may also have exertional dyspnea, but the symptoms that limit activity must be anginal in nature (including chest pain, pressure, heaviness, discomfort, with or without radiation to the neck, jaw, shoulders, arms, or other location) and not dyspnea
- Must have attempted treatment with the maximally tolerated dose of at least three of the four (preferably all four) approved classes of anti-anginal agents: long-acting nitrates, calcium channel blockers (either a dihydropyridine or a non-dihydropyridine), beta blockers, and ranolazine. The regimen must be stable for at least 30 days prior to enrollment, must remain stable from enrollment to randomization, and there must be no intent to change the medical regimen for at least 12 months after randomization Note: If the dose of a medication was increased or decreased for a temporary period and then returned to the original dose, which will then be continued for at least 12 months after randomization, the subject may be immediately enrolled without needing to otherwise requalify
- Subject has either no treatment options for revascularization by coronary artery bypass grafting or by percutaneous coronary intervention, or is otherwise unsuitable or high risk for revascularization as determined by the local heart team, and confirmed by a Central Screening Eligibility Committee
- Evidence of either exercise or pharmacologically induced reversible ischemia severity by stress echo, nuclear study, PET, perfusion MRI, CT perfusion, FFR-CT, FFR, iFR, or other non-hyperemic FDA approved tests (such as diastolic hyperaemia free ratio \[DRF\] or resting full-cycle ratio \[RFR\] in the distribution of the left coronary artery (LCA), performed within 12 months prior to enrollment and while the patient is maintained on their stable regimen of maximally tolerated doses of anti-anginal medications Note: If the subject has evidence of ischemia in both the LCA and RCA distributions, the extent of ischemia must be greater in the LCA distribution Note: The qualifying assessment must be performed after any myocardial infarction, CABG, or successful PCI within the prior 12 months. If the anti-anginal medication regimen is permanently changed after the assessment of ischemia, the test must be repeated. For subjects with multiple assessments, the one performed closest to enrollment will serve as the qualifying study

... and 12 more (see full listing online)

Exclusion (39)

- Recent (within 30 days prior to enrollment) troponin or CKMB positive acute coronary syndrome (NSTEMI or STEMI) Note: subjects with an elevated troponin or CKMB without acute coronary syndrome may still be enrolled
- Recent successful revascularization by either CABG or PCI within six months prior to enrollment
- Note: Successful revascularization is defined as any CABG procedure, or any PCI procedure with a reduction of one or more lesions to \<50% diameter stenosis
- Note: Subjects with successful revascularization by either CABG or PCI that occurred less than six months prior to enrollment may still be approved for participation in the trial if revascularization was completed six months prior to procedure and CSEC approves subject participation
- Recent unsuccessful PCI (e.g., failed attempt to open a chronic total occlusion) within 30 days prior to enrollment

... and 34 more (see full listing online)

Locations (91 total)

https://clinicaltrials.gov/study/NCT05102019

Mayo Clinic, Phoenix, Arizona, United States
HonorHealth Research Institute, Scottsdale, Arizona, United States
University of Arizona Sarver Heart Center, Tucson, Arizona, United States
... and 88 more locations