Assessing the Safety and Effectiveness of Intracoronary Stem Cells in Patients With Refractory Angina

NCT05711849

Status	RECRUITING
Phase	Phase 2
Sponsor	Barts & The London NHS Trust
Enrollment	110 participants

Key Eligibility Criteria

Inclusion (9)

- 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
- Must have attempted treatment with the maximally tolerated dose of at least two of the 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 greater than 2 months prior to enrolment, with no intent to change the medical regimen for at least 12 months after randomisation
- 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
- Evidence of either exercise or pharmacologically induced reversible ischemia severity by stress echo, nuclear study, PET, perfusion MRI, CT perfusion, FFRCT, FFR, iFR, or other non-hyperaemic tests.

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

Exclusion (20)

- Recent (within 30 days prior to enrolment) troponin or CKMB positive acute coronary syndrome (NSTEMI or STEMI).
- Recent successful revascularization by CABG or PCI within six months prior to enrolment
- Recent unsuccessful PCI (e.g., no relief from symptoms, failed attempt to open a chronic total occlusion) within 30 days prior to enrolment
- The predominant manifestation of angina is dyspnoea
- Has extra-coronary contributory causes of angina - e.g., untreated hyperthyroidism, anaemia (hgb \<10 g/dL), uncontrolled hypertension (systolic blood pressure \>160 mmHg or diastolic blood pressure \>100 mmHg despite medications), atrial fibrillation with rapid ventricular response (consistently \>100 bpm despite medications) or other tachyarrhythmia, severe aortic stenosis, hypertrophic cardiomyopathy with left ventricular outflow tract obstruction or asymmetric septal hypertrophy (concentric left ventricular hypertrophy is not an exclusion criterion), etc.

... and 15 more (see full listing online)

Locations (1 total)

St Bartholomew's Hospital, London, England, United Kingdom