

Outcome Research to Confirm the Anti-anginal Effect of T89 in Patients With Stable Angina

NCT03789552

Status	RECRUITING
Phase	Phase 3
Sponsor	Tasly Pharmaceuticals, Inc.
Enrollment	765 participants

Key Eligibility Criteria

Inclusion (19)

- Willing to participate and sign a written informed consent
- Males and females e 18 and d90 years old.
- Medical history of chronic stable angina triggered by physical effort and relieved by rest or sublingual nitroglycerin.
- Patients who agree and in the opinion of the investigator are able to withdraw all non-beta blocker and all non-calcium channel blocker anti-anginal medications. For those subjects who are on beta blockers and/or calcium channel blockers, they are able to keep only one beta blocker or one calcium channel blocker (acceptable calcium channel blocker: amlodipine, diltiazem, verapamil or nicardipine), but not both, and subjects agree and are expected to be able to remain on this treatment regimen from Day -21 until the completion of the double-blind period in the opinion of the investigator.
-) For patients who have to modify their anti-anginal treatment regimen to meet the above qualification criteria, health care provider who is responsible for the patient's cardiac care (if this is not the study doctor) must provide a form of agreement (verbal conversation, phone call, in writing or shown as referral) to the PI before the treatment modification.

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

Exclusion (22)

- Patients with only non-cardiac chest pain or cardiac chest pain not related to angina.
- Patients with contraindication to, unable to, or with other co-morbidities that may prevent or interfere with the ability to perform ETT, in the opinion of investigator, including but not limited to: hospitalization for acute exacerbation of chronic lung disease within 4 weeks prior to the start of screening, current home oxygen use, needs for cardiac glycoside therapy, functionally limiting peripheral arterial disease, physical disability or other intercurrent illness such as acute respiratory infection/illness that, in the opinion of the Investigator or Sub-investigator, may interfere with the ability to perform ETT.
- Patients with presence of electrographic or other abnormalities/factors that could interfere with exercise ECG interpretation or may lead to a false positive stress test (including but not limited to, Lown-Ganong-Levine Syndrome (LGL), Wolff-Parkinson-White Syndrome (WPW), left bundle branch block, e1 mm ST segment depression at rest, pacemaker rhythm etc.).
- *Left ventricular hypertrophy (LVH) without repolarization abnormalities is not considered an exclusion criterion.
- Patients with history of any coronary revascularization procedure (e.g. PCI or CABG) within 2 months prior to the start of screening.

... and 17 more (see full listing online)

Locations (1 total)

Southwest Florida Research LLC, Naples, Florida, United States

<https://clinicaltrials.gov/study/NCT03789552>

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