Safety, Tolerability, and Exploratory Efficacy of AGP100 in Patients With Catecholaminergic Polymorphic Ventricular Tachycardia (CPVT)

NCT07263139

Status	RECRUITING
Phase	Phase 2
Sponsor	Agiana Pharmaceuticals
Enrollment	10 participants

Key Eligibility Criteria

Inclusion (8)

- Signed informed consent prior to any study-related procedures
- Male or female, aged between 18 and 75 years (inclusive)
- Clinical diagnosis of CPVT based on proven RYR2 mutation AND reproducible premature ventricular contraction with exercise or polymorphic or bidirectional ventricular tachycardia with exercise
- Able and willing to undergo exercise testing (bicycle test) AND exhibits exercise-induced ventricular ectopic beats at Screening (at least 1 point on the VA scale)
- On stable, maximum tolerated, dose of non-selective ²blocker for at least 4 weeks before Visit 1. The dosage and choice of ²blocker are to be determined by the patients' physician(s) before entry into the study and must remain unchanged throughout the conduct of the study. Participants taking a stable dose of flecainide for at least 4 weeks, in addition to ²blocker, are also eligible.

... and 3 more (see full listing online)

Exclusion (11)

- Diagnosis of structural heart disease, including coronary artery disease or heart failure with reduced ejection fraction (left ventricular ejection fraction \<45%)
- Participants who have had arrhythmias causing hemodynamic instability at previous exercise tests (performed while on the current standard of care treatment)
- Participants having a sustained VT (VA score of 5) during the exercise tests performed as part of the screening activities
- Participation in another clinical study with an investigational product or device within 60 days of 5 half-lives prior to Baseline (whichever is longer)
- Medical history of severe anaphylactic reactions to any component(s) of the IMP

... and 6 more (see full listing online)

Locations (1 total)

Department of Cardiology, Oslo University Hospital, Oslo, Norway