Efficacy and Safety of Etripamil for the Termination of Spontaneous PSVT. NODE-301

Status: Recruiting

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

1. Male or female patients at least 18 years of age; 2. Electrographically documented history of PSVT (e.g., electrocardiogram [ECG] obtained during an episode of PSVT, Holter monitoring, loop recorder, etc). If patient had a prior ablation for PSVT, patient must have documented ECG evidence of PSVT post-ablation; 3. History of sustained episodes of PSVT (i.e., typically lasting approximately 20 minutes or longer); 4. Females of childbearing potential must agree to use an approved highly effective form of contraception from the time of signed informed consent until 30 days after the last administration of study drug and should have a negative serum pregnancy test result at the Screening Visit, a negative urine pregnancy test at the Test Dose Randomization Visit and must use an approved form of contraception between the 2 visits. Approved forms of contraception include hormonal intrauterine devices, hormonal contraceptives (oral birth control pills, Depo-Provera?, patch, or other injectables) together with supplementary double-barrier methods, such as condoms or diaphragms with spermicidal gel or foam. The following categories define females who are NOT considered to be of childbearing potential:

• Premenopausal females with 1 of the following: 1. Documented hysterectomy, 2. Documented bilateral salpingectomy, or 3. Documented bilateral oophorectomy, or

• Postmenopausal females, defined as having amenorrhea for at least 12 months without an alternative medical cause; 5. Males, except those who are surgically sterile, must use an approved highly effective form of contraception during the 3 days after any study drug administration; and 6. Signed written informed consent.

Exclusion Criteria:

Patients who meet any of the following criteria will be excluded from participation in the study: 1. Systolic blood pressure <90 mmHg after a 5-minute rest in sitting position at the Screening Visit or before the test dose. In patients treated with a chronic prophylactic drug for PSVT (e.g., beta-blockers, verapamil, and diltiazem), the drug may be stopped for at least the equivalent of 5 half-lives and patients may be rescreened once; 2. History of severe symptoms of hypotension, especially syncope, during episodes of PSVT; 3. History of atrial arrhythmia that does not involve the AV node as part of the tachycardia circuit (e.g., atrial fibrillation, atrial flutter, intra-atrial tachycardia); 4. History of allergic reaction to verapamil; 5. Current therapy with digoxin or any Class I or III antiarrhythmic drug, except if these drugs are stopped at least the equivalent of 5 half-lives before the Test Dose Randomization Visit; 6. Current therapy with amiodarone, or have taken amiodarone within 30 days prior to the Test Dose Randomization Visit; 7. Evidence of ventricular pre-excitation (e.g., delta waves, short PR interval <100 msec, Wolff-Parkinson-White syndrome) on the ECG performed at the Screening Visit or before the test dose administration; 8. Evidence of a second- or third-degree AV block on the ECG performed at the Screening Visit o before the test dose administration; 9. History or evidence of severe ventricular arrhythmia (e.g., torsades de pointes, ventricular fibrillation, or sustained ventricular tachycardia); 10. Current congestive heart failure defined by the New York Heart Association Class II to IV; 11. Stroke in the last 6 months; 12. Evidence of hepatic dysfunction defined as alanine aminotransferase or aspartate aminotransferase >3 ? the upper limit of normal (ULN) or total bilirubin >2 ? ULN at the Screening Visit, unless due to Gilbert syndrome; 13. Evidence of renal dysfunction as determined by an estimated glomerular filtration rate assessed at the Screening Visit as follows: 1. <60 mL/min/1.73 m2 for patients <60 years of age; 2. <40 mL/min/1.73 m2 for patients ?60 and <70 years of age; or 3. <35 mL/min/1.73 m2 for patients ?70 years of age; 14. Females who are pregnant or lactating; 15. Evidence or history of any significant physical or psychiatric condition including drug abuse, which, in the opinion of the Investigator, could jeopardize the safety of patients, or affect their participation in the study. Additionally, the Investigator has the ability to exclude a patient if for any reason the Investigator judges the patient is not a good candidate for the study or will not be able to follow study procedures; 16. Current participation in any investigational drug or device study or the use of any investigational drug or device within 30 days of the Screening Visit. Before randomization, all patients will receive a test dose of etripamil NS 70 mg to evaluate tolerability and to train patients for the procedures. A failure of the test dose is considered if patients meet any of the following criteria occurring after administration of the etripamil NS 70 mg test dose: 1. Any symptoms consistent with clinically severe hypotension such as pre-syncope, medically significant lightheadedness, syncope, nausea, or vomiting; 2. For patients with a pre-test dose Systolic Blood Pressure above 100 mmHg: 1. Decrease in SBP ?40 mmHg after test dose; or 2. Post-test dose SBP <80 mmHg; 3. For patients with a pre-test dose SBP between 90 mmHg and 100 mmHg (inclusive): a) Post-test dose SBP <75 mmHg; 4. Third-degree AV block, Mobitz II second-degree AV block, or Wenckebach with bradycardia ?40 bpm; 5. New, significant sinus bradycardia Heart Rate ?40 bpm or sinus pauses (?3 seconds), if considered by the Investigator to put the patient's safety at risk if either were to occur while not under medical supervision; 6. Any new significant ventricular arrhythmia (premature ventricular beats and couplets [>6 premature ventricular contractions per 45 seconds ECG] are considered significant); and 7. Atrial fibrillation or atrial flutter (event lasting longer than 30 seconds). Patients who fail the test dose will proceed in the study as follows:

• If the Investigator identifies a possible reversible cause of the initial test dose failure (e.g., concomitant medication such as beta-blocker), a re-challenge with a new test dose of etripamil NS 70 mg will be possible after elimination of the reversible cause (e.g., withdrawal of concomitant therapy with the appropriate washout period). Patients may be randomized if they pass the second test dose and the cause of the test dose failure is eliminated for the duration of the study; or

• If the Investigator cannot identify a reversible cause of the initial test dose failure, or if the potential cause cannot be modified (e.g., necessary antihypertensive drug to control blood pressure), patients will not be randomized and will complete a Final Study Visit. Patients who fail the test dose will be part of the Test Dose Only Population, including all patients who received at least 1 test dose of etripamil NS 70 mg

Conditions & Interventions

Interventions:
Drug: Etripamil, Drug: Placebo, Device: Aptar Pharma Nasal Spray
Conditions:
Paroxysmal Supraventricular Tachycardia
Keywords:
Paroxysmal supraventricular tachycardia, cardiac monitoring, atrioventricular nodal reentrant tachycardia, atrioventricular reciprocating tachycardia, calcium channel blocker, conversion rate

More Information

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System ID: NCT03494010

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