The NODE-202 Study (Study of Etripamil Nasal Spray in Pediatric Patients)

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 6 years to 17 years old
Healthy Volunteers: This study is NOT accepting healthy volunteers
Inclusion Criteria:

Patients will be eligible for study participation if they meet all of the following criteria at screening:

1. Male or female patients
    1. Part 1: patients 12 to <18 years of age
    2. Part 2: patients 6 to <12 years of age
2. Body mass index (BMI) between the 5th and the 85th percentiles interpreted relative sex and age
3. History of PSVT documented by ECG or other monitoring modality (e.g., Holter monitor, event recorder) showing SVT involving the Atrioventricular (AV) node (i.e., Atrioventricular nodal reentry tachycardia (AVNRT) or Atrioventricular reentrant tachycardia (AVRT)). If patient had a prior ablation for PSVT, patient must have documented evidence of PSVT post-ablation
4. Signed written informed consent/assent obtained
5. Per Investigator's decision, females of childbearing potential (defined as any woman or adolescent who has begun menstruation) must additionally satisfy the following criteria:
    1. Negative pregnancy test at screening
    2. Adequate contraception, unless total abstinence is used
6. Willing and able to comply with study procedures.

Exclusion Criteria:

Patients will be excluded from the study if they meet any of the following criteria:

1. History or presence of any of the following at the screening visit:
    1. Patients with a history of atrial arrhythmia that does not involve the AV node as part of the tachycardia circuit (e.g., atrial fibrillation, atrial flutter, atrial tachycardia) are not eligible
    2. Permanent junctional reciprocating tachycardia
    3. Ventricular pre-excitation (e.g., delta wave on ECG, Wolff Parkinson White syndrome)
    4. Second- or third-degree AV block
    5. Sick sinus syndrome or clinically significant bradycardia (<50 bpm or equivalent in this patient population) on the resting ECG
    6. Ventricular tachycardia
    7. Long QT syndrome
    8. Major structural heart disease (e.g., Ebstein's anomaly, corrected congenital heart disease) or symptoms of congestive heart failure (New York Heart Association class II to IV).
2. Evidence of impaired liver function (alanine aminotransferase [ALT] and/or aspartate aminotransferase [AST] >3 x upper limit of normal for age and gender) at the Screening Visit
3. Evidence of End-Stage Renal Disease as determined by an estimated glomerular filtration rate assessed at the Screening Visit of <15 mL/min/1.73m2, or requiring hemodialysis;
4. Treatment with any of the following that cannot or will not be discontinued during study participation:
    1. Any investigational drug within 60 days prior to study drug administration
    2. IV beta-adrenergic blocking drugs (e.g., propranolol, esmolol), calcium channel blocking drugs (e.g., verapamil, diltiazem) or amiodarone within 24 hours prior to study drug administration
    3. Oral amiodarone within 30 days prior to study drug administration
    4. Class I or III antiarrhythmic agents (e.g., flecainide, propafenone, sotalol) within five half-lives prior to study drug administration
    5. Any other drug that has a contraindication with verapamil
5. Known hypersensitivity to verapamil or to any of the excipients of the study drug
6. Any other significant co-morbid condition that may have a negative impact on the patient's participation in the study or likely to result in non-compliance
7. History of hyperthyroidism
8. Current pregnancy or breastfeeding

Conditions & Interventions

Interventions:
DRUG: Etripamil NS
Conditions:
Paroxysmal Supraventricular Tachycardia
Keywords:
PSVT

More Information

Description:
NODE-202 is a Phase 2, multicenter, multinational, single dose, open-label, 2-part, sequential design study in pediatric patients with an established diagnosis of paroxysmal supraventricular tachycardia (PSVT) presenting with a symptomatic episode of PSVT. In Part 1, at least 30 patients aged 12 to \<18 years will be enrolled and treated with etripamil nasal spray (NS). Efficacy, safety, tolerability and PK (for at least 12 patients) will be assessed after administration of 70 mg etripamil NS (Part 1A). At least 18 subsequent patients will be enrolled and treated with the etripamil NS with the dose determined by the Pharmacokinetic (PK) analysis and will undergo efficacy and safety/tolerability assessments (Part 1B). In Part 2, at least 30 patients aged 6 to \<12 years will be enrolled and treated with etripamil NS at a dose selected based on appropriate body size-based modeling, as well as efficacy, safety/tolerability, and PK data collected in Part 1. Efficacy, safety, tolerability and PK (for at least 12 patients) will be assessed after administration of etripamil NS (Part 2A). At least 18 subsequent patients will be enrolled and treated with the etripamil NS with the dose determined by the PK analysis and will undergo efficacy and safety/tolerability assessments (Part 2B). The study will include the following visits: A Screening Visit, A Treatment Visit, , and A Follow-Up/End of Study Visit.

Contact(s): Allison Ackermann - allison.ackermann@cchmc.org
Principal Investigator:
Principal Investigator ID:
Phase: PHASE2
IRB Number:
System ID: NCT05763953
