

Registry of Etripamil (CARDAMYST™) Studies Evaluating Treatment in Paroxysmal Supraventricular Tachycardia (RESET-PSVT): Study Design



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Background

- Paroxysmal supraventricular tachycardia (PSVT) is an arrhythmia marked by sudden, intermittent episodes of a rapid heart rate, typically ranging from >100 to 250 beats per minute (bpm) (Table 1).¹⁻⁴

TABLE 1. PSVT CHARACTERISTICS

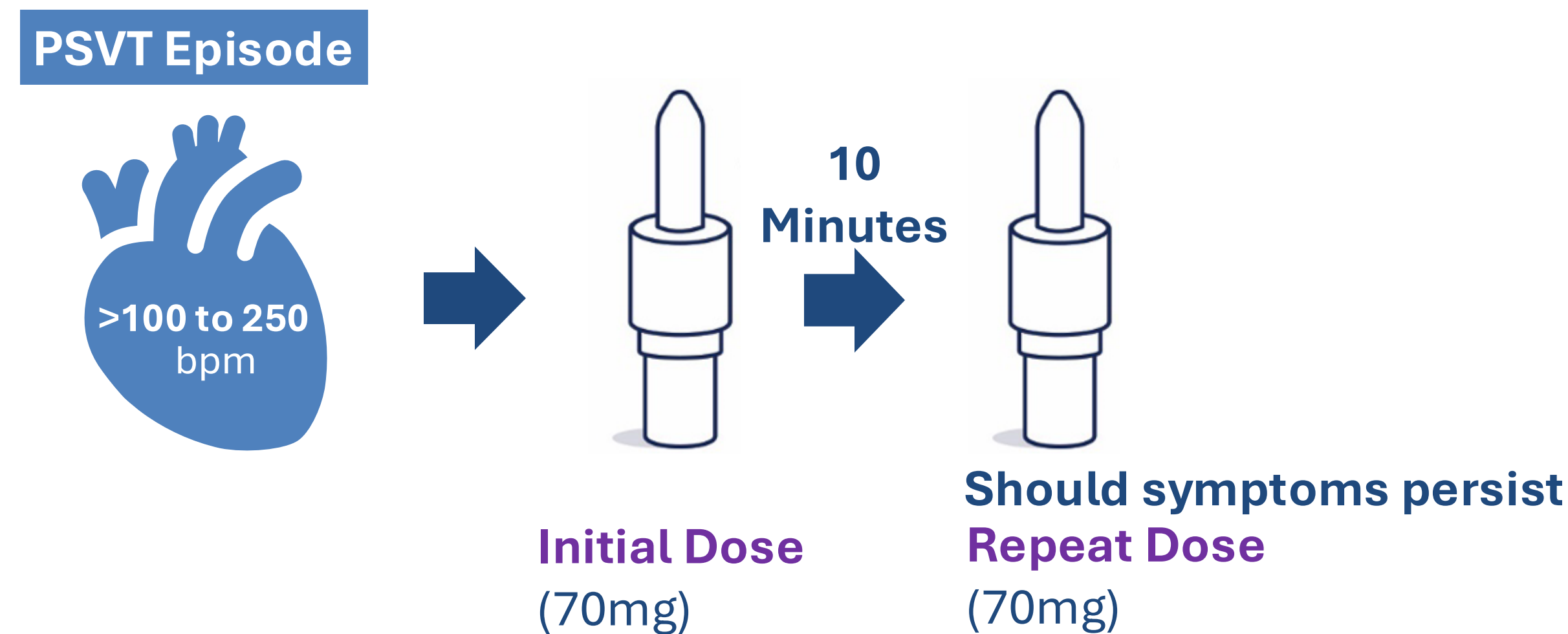
Paroxysmal Supraventricular Tachycardia (PSVT) ¹⁻⁴
Regular heart rate
>100 to 250 bpm
Episode frequency and duration are highly variable

- PSVT affects 1 in 300 people in the U.S. and leads to over 200,000 emergency department (ED) visits annually, frequently for intravenous medications (i.e., adenosine or CCBs) and resulting in high expenditures and healthcare resource utilization.⁵
- Common symptoms include heart palpitations, fatigue, shortness of breath, chest pressure or pain, light-headedness, and anxiety.⁴

Intervention

- CARDAMYST™ is a calcium channel blocker indicated for the conversion of acute symptomatic episodes of PSVT to sinus rhythm in adults.⁶
- CARDAMYST is self-administered as a single 70mg dose, with an optional repeat dose after 10 minutes if symptoms persist (Figure 1).⁶
- Clinical trials have consistently demonstrated the safety and efficacy of CARDAMYST (investigational drug name etripamil), though post-approval real-world use has not been studied.

FIGURE 1. CARDAMYST NASAL SPRAY



- In the pivotal Phase 3 clinical trial (RAPID), Kaplan-Meier estimates of conversion rates by 30 minutes were 64% with etripamil and 31% with placebo.⁷
- Median time to conversion was 17.2 minutes with etripamil and 53.5 minutes with placebo.⁷
- Adverse events occurring in ≥5% of patients treated with etripamil were nasal discomfort (23%), nasal congestion (13%), and rhinorrhea (9%).⁷
- No serious etripamil-related adverse events or deaths were reported.⁷

Objective

To generate prospective evidence to inform the real-world use of recently approved CARDAMYST and demonstrate its potential impact on the acute management of PSVT.

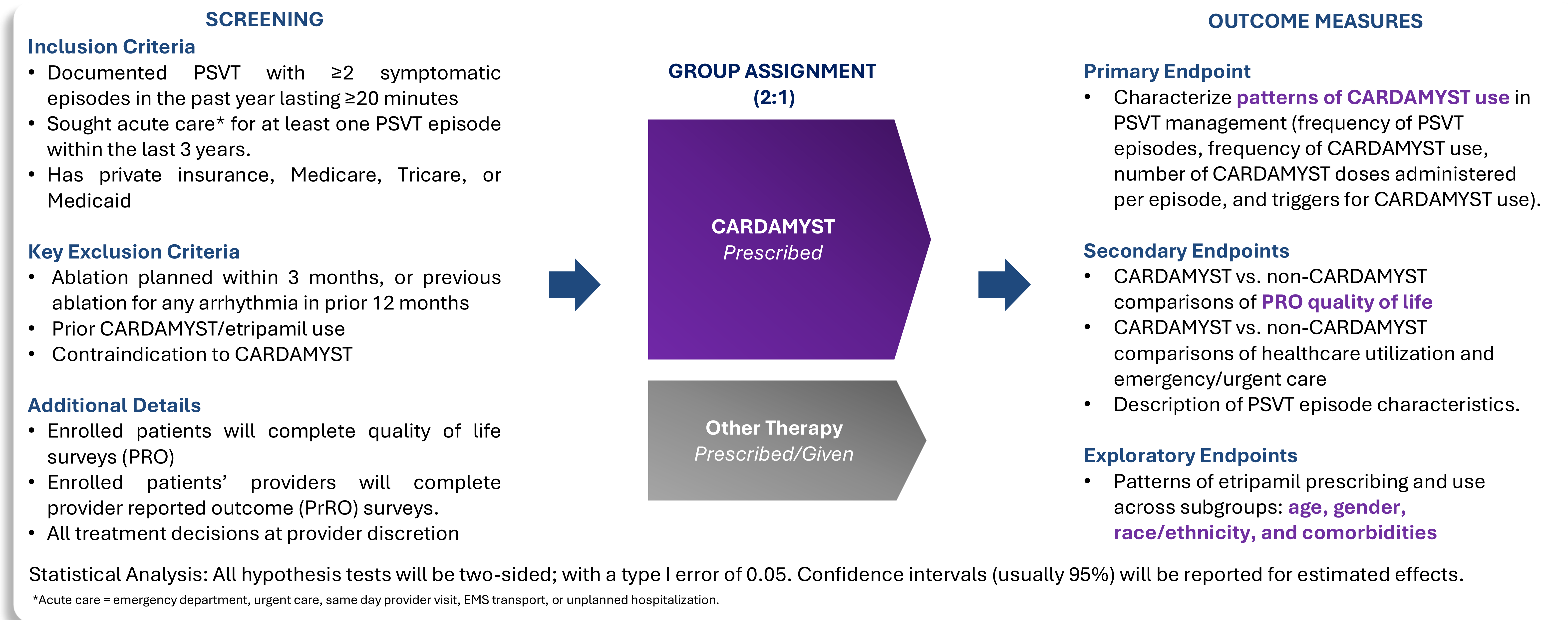
Methods

RESET-PSVT is a planned phase 4, multicenter, prospective, observational study designed to capture patterns of use of CARDAMYST (Figure 2).

Study Overview

- Total expected enrollment of N=450 participants, all ≥18 years old with documented PSVT; inclusion/exclusion criteria described below.
- 2:1 allocation of patients who have been prescribed CARDAMYST vs. those prescribed or given other therapy (not prescribed CARDAMYST).
- Planned 20 electrophysiology (EP)/cardiology sites with enrollment planned to start in 2026.

FIGURE 2. RESET-PSVT Study Design Phase 4



Discussion

- RESET-PSVT, the first Phase 4 study of CARDAMYST and first contemporary PSVT registry, will compare PSVT patients with and without CARDAMYST treatment.
- Results will be communicated at scientific conferences and in peer-reviewed publications.

Limitations

- There is a potential for PRO recall bias due to the time between PSVT events and data collection. However, this will be mitigated by the suggested patient reporting in proximity to events and use of patient post-episode diaries.
- The absence of randomization and controlled intervention, renderings the study susceptible to selection bias, residual confounding, and reduced internal validity for causal inference.

Implications for Practice

RESET-PSVT will generate prospective evidence to inform the real-world use of recently approved CARDAMYST and demonstrate how it can impact the acute management of PSVT.

References

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