CardiolTherapeutics

MAvERIC-Pilot Study: HCP Reference Card

ClinicalTrials.gov Identifier: NCT05494788

Study Overview

- MAvERIC-Pilot is a Phase 2 multi-center, open-label, pilot study assessing the impact of CardiolRx™ (cannabidiol) oral solution, on recurrent pericarditis
- Participants will be enrolled in the study for approximately 26 weeks
- Participants will be expected to attend 9 clinic visits, of which up to 5 could be completed virtually under specific conditions

Study Intervention

- CardiolRx™ is a pharmaceutically manufactured synthetic cannabidiol solution, formulated for oral administration
- All participants will receive CardiolRx™ twice per day for 8 weeks
- If there is no contraindication, participants will continue study treatment for an additional 18 weeks and concomitant medications for pericarditis will be weaned

Primary Objective

- To evaluate the effect of CardiolRx™ on patient-reported pericarditis pain score using an 11-point Numerical Rating Scale (NRS), following 8 weeks of treatment

Safety Objective

- To demonstrate that administration of CardiolRx™ in the proposed doses in this patient population is safe, as determined by measuring several parameters

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Eligibility

Key Inclusion Criteria

- Male or female patients aged ≥18 years
- Diagnosis of at least 2 episodes of recurrent pericarditis
- At least 1 day with pericarditis pain score ≥4 on the 11-point NRS within the prior 7 days
- C-reactive protein level ≥1.0 mg/dL OR evidence of pericardial inflammation assessed by delayed pericardial hyperenhancement on cardiac magnetic resonance imaging (MRI)
- Currently receiving non-steroidal anti-inflammatory drugs (NSAIDs), colchicine or corticosteroids for treatment of pericarditis (in any combination) in stable doses

Key Exclusion Criteria

- Diagnosis of pericarditis secondary to the following etiologies:
  - Tuberculosis
  - Neoplastic, purulent or radiation etiology
  - Post-thoracic blunt trauma
  - Myocarditis
- Prior history of sustained ventricular arrhythmias or QT interval prolongation
- Taken any cannabinoid in the past month
- Current diagnosis of cancer (except for non-melanoma skin cancer)
- Immunosuppressive therapy with any of the following treatments: rilonacept; anakinra; canakinumab; methotrexate; azathioprine; cyclosporine; intravenous immune globulin (IVIG)

More details are available in the study protocol. Please note that the ultimate reference for eligibility is the protocol.