CardiolRx in Recurrent Pericarditis Following IL-1 Blocker Cessation

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

1. Patients 18 years of age or older 2. A history of recurrent pericarditis with stable disease and currently being treated with an IL-1 blocker, scheduled to be discontinued. Stable disease is defined as: * treatment with an IL-1 blocker for at least 12 months, * free of pericarditis recurrence for at least 6 months and this recurrence, if present, must have occurred in the setting of an interruption or tapering of an IL-1 blocker; and * treatment with an unchanged dose and regimen of on an IL-1 blocker for at least 3 months prior to randomization. 3. Pericarditis pain les or equal than 2 on the 11-point Numerical Rating Scale (NRS) for at least 7 days prior to randomization (Visit 1, Day 1) 4. C-Reactive Protein (CRP) \< 1.0 mg/dL during screening within 7 days prior to randomization (Visit 1, Day 1). 5. Patients who have had a vasectomy or who are willing to use double barrier contraception methods with partners of childbearing potential during the conduct of the trial and for 2 months after the last dose of trial therapy. 6. Patients of childbearing potential willing to use an acceptable method of contraception starting with trial therapy administration and for a minimum of 2 months after trial completion. Otherwise, these patients must be postmenopausal (at least 1 year absence of vaginal bleeding or spotting and confirmed by follicle stimulating hormone \[FSH\] ≥ 40 mIU/mL \[or ≥ 40 IU/L\] if less than 2 years postmenopausal) or be surgically sterile. Acceptable birth control methods that result in a failure rate of less than 1 % include oral, intravaginal or transdermal combined (estrogen and progestogen containing) hormonal contraception associated with inhibition of ovulation; oral, injectable or implantable progestogen-only hormonal contraception associated with inhibition of ovulation; intrauterine device (IUD); intrauterine hormone-releasing system (IUS); using double-barrier contraception methods with their partners; bilateral tubal occlusion; vasectomised partner; sexual abstinence.

Exclusion Criteria:

1. Pericarditis recurrence(s) during IL-1 blocker treatment without interruption or tapering of the IL-1 blocker 2. Diagnosis of pericarditis that is secondary to specific prohibited etiologies, including tuberculosis (TB); neoplastic, purulent, or radiation etiologies; post-thoracic blunt trauma (e.g., motor vehicle accident); systemic autoimmune disease (e.g., systemic lupus erythematosus) 3. Primary diagnosis of myocarditis (diagnosis of myopericarditis is accepted) 4. Estimated glomerular filtration rate (eGFR) \< 30 mL/min during screening within 7 days prior to randomization (Visit 1, Day 1) 5. Elevated alanine aminotransferase (ALT) or aspartate aminotransferase (AST) \> 5 times the upper limit of normal (ULN) or ALT or AST \> 3x ULN plus bilirubin \> 2x ULN during screening within 7 days prior to randomization (Visit 1, Day 1). 6. Sepsis, defined as documented bacteremia during screening within 7 days prior to randomization (Visit 1, Day 1) or other untreated or uncontrolled bacterial infection* 7. Prior history of sustained ventricular arrhythmia(s) 8. History of diagnosed long QT syndrome 9. QTc interval \> 480 msec (biologically female) or \> 470 msec (biologically male) (please refer to Section 9.2.3 for bundle branch block, bifascicular block and paced rhythm correction) or second or third degree atrioventricular (AV) block in a patient without an implanted functioning pacemaker device during screening within 7 days prior to randomization (Visit 1, Day 1) 10. Showing suicidal tendency during the last 12 months, as defined by answering "yes" to question 4 or 5 of the Columbia Suicide Severity Rating Scale (C-SSRS), administered during screening within 7 days prior to randomization (Visit 1, Day 1) 11. Participation in a clinical trial in which an investigational drug or device was administered within 30 days of screening or within 5 half-lives of the previous study drug, whichever is longer 12. Inability or unwillingness to give informed consent 13. Ongoing drug or alcohol abuse in the opinion of the investigator 14. On any cannabinoid during the past month or unwilling to stay abstinent from all cannabis products for the duration of the trial 15. Pregnant or breastfeeding 16. Current diagnosis of active cancer, with the exception of non-melanoma skin cancer 17. Any factor, which would make it unlikely that the patient can comply with the trial procedures 18. Moderate (Child-Pugh B) or severe (Child-Pugh C) hepatic impairment 19. Has received systemic immunomodulatory agents as below prior to randomization: 1. Methotrexate (within 2 weeks) 2. Azathioprine, mycophenolate mofetil, cyclosporine, tacrolimus, sirolimus, or mercaptopurine (within 24 weeks) 3. Canakinumab, TNF inhibitors, IL-6 inhibitors, or janus-activating kinase inhibitors (within 12 weeks) 4. Intravenous immune globulin (IVIG) (within 8 weeks) 5. Corticosteroids (within 4 weeks) 20. Known hypersensitivity to the active substance or any of the excipients of the trial

Conditions & Interventions

Interventions:
DRUG: CardiolRx
Conditions:
Recurrent Pericarditis
Keywords:
IL-1 blocker-dependent recurrent pericarditis, pharmaceutically cannabidial

More Information

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