

Cardiac Sarcoidosis Randomized Trial

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

(i) Cardiac sarcoidosis presenting with one or more of the following clinical findings: * advanced conduction system disease (defined as Mobitz II AV block or third degree AV block) * significant sinus node dysfunction (defined as average HR less than 40bpm when awake and/or sustained atrial arrhythmias) * non- sustained or sustained ventricular arrhythmia * left ventricular dysfunction (LVEF \leq 50%) * right ventricular dysfunction (RVEF \leq 40%) AND (ii) No alternative explanation for clinical features AND (iii) Nuclear Imaging within six-months of enrollment consisting of FDG-PET scan with FDG uptake suggestive of active CS and myocardial perfusion imaging AND ONE OR BOTH OF FOLLOWING (iv) Positive biopsy for Sarcoid (either EMB or extra-cardiac) (v) CT Chest showing features consistent with pulmonary sarcoidosis and/or mediastinal and/or hilar lymphadenopathy

Exclusion Criteria:

1. Current or recent (within two months) non-topical treatment for sarcoidosis 2. Current Oral/IV treatment of duration greater than 5 days 3. Currently taking Methotrexate or Prednisone for another health condition 4. Intolerance or contra-indication to Methotrexate or Prednisone 5. Patient does not meet all of the above listed inclusion criteria 6. Patient is unable or unwilling to provide informed consent 7. Patient is included in another randomized clinical trial 8. Patient has a contraindication to PET imaging or is unlikely to tolerate due to severe claustrophobia 9. Pregnancy (all women of child bearing age and potential will have a negative BHCG test before enrollment) 10. Breastfeeding 11. Women of childbearing age who refuse to use a highly effective and medically acceptable form of contraception throughout the study 12. Patients for whom the investigator believes that the trial is not in the interest of the patient

Conditions & Interventions

Interventions:

DRUG: Prednisone or Prednisolone, DRUG: Methotrexate

Conditions:

Cardiac Sarcoidosis, Sarcoidosis

Keywords:

Cardiac Sarcoidosis, Prednisone (or Prednisolone), Methotrexate

More Information

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Phase: PHASE3

IRB

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