At-home Ultrasound Localized Therapy for Rheumatoid Arthritis Study

Status: Recruiting

Eligibility Criteria

Sex: Male or Female
Age Group: 18 years and over
This study is NOT accepting healthy volunteers

Inclusion Criteria:

- active moderate to severe seropositive rheumatoid arthritis (RA) - have at least 6 total tender and/or swollen joints - receiving stable background treatment with a csDMARD (e.g. methotrexate) for at least 8 weeks prior to start of the study. Participants must be willing to maintain their background medication regimen throughout the 28-week study period - may receive up to 10 mg of daily prednisone as part of treatment but must have maintained a stable dose for a minimum of 6 weeks prior to start of the study and be willing to maintain the stable dose until after the Week 24 of the study - see link to clinicaltrials.gov for complete Inclusion criteria

Exclusion Criteria:

- women who are pregnant or trying to get pregnant - active bacterial or viral infection - implanted device or other solid object on the spleen side of the torso - recent abdominal surgery - see link to clinicaltrials.gov for complete Exclusion criteria

Conditions & Interventions

Interventions:
Drug: Conventional Synthetic DMARD, Device: Non-invasive ultrasound stimulation of the spleen - Treatment Setting 1, Device: Non-invasive ultrasound stimulation of the spleen - Treatment Setting 2, Device: Sham ultrasound stimulation (control)
Conditions:
Arthritis & Rheumatic Diseases
Keywords:
RA, rheumatoid arthritis, spleen, stimulation, treatment, Ultrasound

More Information

Description: The research objective is to evaluate performance of ultrasound stimulation of the spleen for the treatment of rheumatoid arthritis (RA). In particular, a new wearable ultrasound device has been developed for anti-inflammatory treatment by a company called SecondWave Systems. We will measure RA disease activity, biomarkers and clinical metrics for up to 24 weeks of investigational ultrasound treatment.
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Phase: NA
IRB Number: STUDY00025536