The Effects of IL-1 Blockade on Inotrope Sensitivity in Patients With Heart Failure (AID-HEART)

Status: RECRUITING

Eligibility Criteria

Age: 21 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Primary diagnosis for the clinic visit is stage D heart failure being on chronic stable dose of inotrope therapy (dobutamine or milrinone for the previous 28 days) * Prior documentation of impaired left ventricular systolic function (ejection fraction \<50%) at most recent assessment by any imaging modality (within 12 months) * Stable dose of inotrope treatment without a recent hospitalization within the previous month * Age ≥21 years and willing/able to provide written informed consent * The patient is willing and able to comply with the protocol (i.e. self administration of the treatment, and exercise protocol). * Screening plasma C-reactive protein levels \>2 mg/L

Exclusion Criteria:

* Concomitant clinically significant comorbidities including (but not limited to) acute coronary syndromes, uncontrolled hypertension or orthostatic hypotension, tachy- or brady-arrhythmias, acute or chronic pulmonary disease or neuromuscular disorders affecting respiration that would interfere with the execution, interpretation, or completion of the study * Recent (previous 3 months) or planned resynchronization therapy (CRT), or valve surgeries * Previous or planned implantation of left ventricular assist devices or heart transplant within the next 3 months * Recent (\<14 days) use of immunosuppressive or anti-inflammatory drugs (including oral corticosteroids at a dose of prednisone equivalent of 0.5 mg/kg/day but not including inhaled or low dose oral corticosteroids or non-steroidal anti-inflammatory drugs) * Chronic inflammatory disorder (including but not limited to rheumatoid arthritis, systemic lupus erythematosus) * Active infection (of any type), including chronic/recurrent infectious disease (including HBV, HCV, and HIV/AIDS)

•but excluding HCV+ with undetectable plasma RNA * Prior (within the past 5 years) or current malignancy on targeted treatment

•excluding carcinoma in situ \[any location\] or localized non-melanoma skin cancer * Stage V kidney disease or on renal-replacement therapy * Neutropenia (\<1,500/mm3 or \<1,000/mm3 in African-American patients) * Pregnancy or breastfeeding * Angina, hypertension, arrhythmias, electrocardiograph (ECG) changes, or other non-cardiac limitations that limit 6MWD obtained during the baseline testing * Hypersensitivity to anakinra or to E. coli derived products

Conditions & Interventions

Interventions:
DRUG: Anakinra
Conditions:
Heart Failure
Keywords:
Inotrope sensitivity, IL-1 Blockade, Subcutaneous (SC), Hepatitis B Virus (HBV), Hepatitis C Virus (HCV, 6 Minute Walk Test (6MWT)

More Information

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