MYTHS - MYocarditis THerapy With Steroids

Status: RECRUITING

Eligibility Criteria

Age: 18 years to 69 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Patients admitted to hospital for suspected AM * Age 18 years or older and below 70 years (18-69 years) * Acute HF with clinically suspected acute myocarditis based on an N-terminal pro-B-type natriuretic peptide (NT-proBNP) concentration of 1600 pg/mL or more or a B-type natriuretic peptide (BNP) concentration of 400 pg/mL or more; * Left ventricular ejection fraction (LVEF)\<41% and left ventricular end diastolic diameter (LV-EDD)\<56 mm (parasternal long-axis view) on echocardiogram; * Increased troponin (3x upper reference limit \[URL\]) at the time of randomization; * Clinical onset of cardiac symptoms within 3 weeks from randomization; * Excluded coronary artery disease by coronary angiogram in subjects ≥46 years of age, in case myocarditis is not histologically proven; * Randomization within 120 hours from hospital admission.

Exclusion Criteria:

* Known systemic autoimmune disorder or other conditions at the time of randomization where immunosuppression is assumed useful. Patients in whom a systemic autoimmune disorder will be diagnosed during hospitalization will be included in the study if randomized, including patients with a diagnosis of cardiac sarcoidosis or giant cell myocarditis (GCM). Both patients included in the corticosteroids-treatment arm or in the placebo-treatment arm can receive the standard immunosuppressive therapy used in the center since the diagnosis of a systemic autoimmune disorder, or cardiac sarcoidosis or GCM; * Patients already on oral/IV chronic corticosteroid therapy or other chronic immunosuppressive therapies (colchicine or nonsteroidal anti-inflammatory drugs \[NSAIDs\] are not considered immunosuppressive drugs); * Contraindication to corticosteroids, including allergies to this medication and its excipients; * Patients with persistent peripheral eosinophilia (persistent Eosinophil count \>7% of the leukocytes) or known hypereosinophilic syndrome at the time of randomization. Patients in whom eosinophilic myocarditis will be diagnosed on endomyocardial biopsy (EMB) will be included in the study if already randomized. Both patients included in the corticosteroids-treatment arm or in the placebo-treatment arm can receive the standard immunosuppressive therapy used in the center since the diagnosis; * Myocarditis associated with the ongoing administration of anti-cancer immune checkpoint inhibitor (ICI) agents; * Previously known chronic cardiac disease (i.e., previous cardiomyopathy) that does NOT include previous myocarditis if there is a functional recovery at the time of screening); * Evidence of active bacterial or fungal infectious disease (presence of fever or increased C-reactive protein are not considered exclusion criteria), or suspected bacterial/fungal infection associated with increased levels of procalcitonin (cut-off \>10 ng/mL), if the laboratory exam is available in the center; * Known chronic infective disease, such as HIV infection or tuberculosis; * out-of-hospital cardiac arrest; * t-MCS instituted more than 48 hours before randomization; * Patients clinically judged too sick to initiate t-MCS (i.e., irreversible multiorgan failure); * Echocardiographic presence of images suggestive of other cardiac diseases (i.e. endocarditis) * Participants involved in another clinical trial; * Pregnant women (known pregnancy) or POSITIVE human chorionic gonadotropin (HCG) test measures (urine/blood) for women of 18-50 years of age. * Any other significant disease with expected life expectancy \<12 months (i.e., evidence of irreversible severe brain injury) or disorder which, in the opinion of the Investigator, may either put the participants at risk because of participation in the trial, or may influence the result of the trial, or the participant's ability to participate in the trial.

Conditions & Interventions

Interventions:
DRUG: Methylprednisolone, DRUG: saline solution
Conditions:
Myocarditis Acute
Keywords:
Acute Myocarditis, Corticosteroid therapy, Myocarditis, Trial, Immunosuppression, Acute heart failure, Fulminant acute myocarditis

More Information

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