Abatacept in Immune Checkpoint Inhibitor Myocarditis

NCT05335928

Status	RECRUITING
Phase	Phase 3
Sponsor	Massachusetts General Hospital
Enrollment	390 participants

Key Eligibility Criteria

Inclusion (13)

• Must have provided informed consent in a manner approved by the Investigator's Institutional Review Board (IRB) prior to any study-related procedure being performed. If a participant is unable to provide informed consent due to his/her medical condition, the participant's legally authorized representative may consent on behalf of the study participant, as permitted by local law and institutional Standard Operating Procedures;

• Aged greater than or equal to 18 years at the time of informed consent;

• Recent use of an FDA-approved immune checkpoint inhibitor (ICI, defined as administered an immune checkpoint inhibitor d 6 months of myocarditis diagnosis), alone or in combination with other cancer therapies (i.e. chemotherapy, radiation therapy or targeted therapy). The FDA-approved ICI could be given as part of a clinical trial but not in combination with a new investigational agent which may cause myocarditis;

• A diagnosis of myocarditis.

• Hospitalized at the time of randomization;

... and 8 more (see full listing online)

Exclusion (14)

• Must not have experienced any of the following (as defined in the section on the primary endpoint) in the 30-day period prior to randomization:

• A sudden cardiac arrest

• Cardiogenic shock as defined. A significant bradyarrhythmia (Mobitz type II second degree atrioventricular block or third degree (complete) atrio-ventricular (AV) block, for which an intervention with a temporary or permanent pacemaker is completed or recommended).

• A significant tachyarrhythmia (ventricular fibrillation of any duration or sustained ventricular tachycardia (\>30 seconds, \>120 beats per minute); or a ventricular tachyarrhythmia requiring intervention.

• Recent (d2 month) exposure to abatacept or belatacept.

... and 9 more (see full listing online)

Locations (31 total)

Cedars-Sinai Medical Center, Los Angeles, California, United States
University of California Los Angeles, Los Angeles, California, United States
MedStar Health Research Institute, Georgetown University, Washington D.C., District of Columbia, United States
... and 28 more locations