

RESET-Myositis: An Open-Label Study to Evaluate the Safety and Efficacy of CABA-201 in Subjects With Active Idiopathic Inflammatory Myopathy or Juvenile Idiopathic Inflammatory Myopathy

NCT06154252

Status	RECRUITING
Phase	Phase 2, Phase 3
Sponsor	Cabaletta Bio
Enrollment	74 participants

Key Eligibility Criteria

Inclusion (11)

- Adult Cohorts
 - Age e18 and d75
 - A clinical diagnosis of IIM, based on the 2017 The European League Against Rheumatism/American College of Rheumatology classification criteria
 - Diagnosis of DM, ASyS, or IMNM
 - Evidence of active disease, despite prior or current treatment with standard of care treatments, as defined by the presence of elevated creatine kinase (CK), DM rash, or active disease on muscle biopsy, magnetic resonance imaging (MRI), or electromyography
- ... and 6 more (see full listing online)

Exclusion (19)

- Contraindication to leukapheresis
 - History of anaphylactic or severe systemic reaction to fludarabine, cyclophosphamide or any of their metabolites
 - Active infection requiring medical intervention at screening
 - Current symptoms of severe, progressive, or uncontrolled renal, hepatic, hematological, gastrointestinal, pulmonary, psychiatric, cardiac, neurological, or cerebral disease, including severe and uncontrolled infections, such as sepsis and opportunistic infections
 - Concomitant medical conditions that, in the opinion of the investigator, might place the subject at unacceptable risk for participation in this study, interfere with the assessment of the effects or safety of the investigational product or with the study procedures
- ... and 14 more (see full listing online)

Locations (32 total)

University of California Irvine - Accepting Adult Patients, Orange, California, United States
University of California, San Francisco Benioff Children's Hospital - Accepting Young Adult and Juvenile Patients, San Francisco, California, United States
Children's Hospital Colorado - Accepting Juvenile Patients, Aurora, Colorado, United States
... and 29 more locations

<https://clinicaltrials.gov/study/NCT06154252>

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