

Safety and Efficacy of ULSC on Disease Severity and Steroid Tapering in Participants With Dermatomyositis/ Polymyositis (DM/PM), Also Known as Idiopathic Inflammatory Myopathy (IIM)

NCT07160205

Status	RECRUITING
Phase	Phase 2, Phase 3
Sponsor	Restem, LLC.
Enrollment	40 participants

Key Eligibility Criteria

Inclusion (24)

- Participants will be e18 years old.
- Diagnosis of idiopathic inflammatory myositis (IIM) based on 2017 EULAR/ACR Classification Criteria for adult IIM, corresponding to a score of e 5.5 (e 6.7 with muscle biopsy).
- Active disease as defined by any one of the following test results:
- Elevated Creatine Kinase (CK) or Aldolase (more than 1.5 x the upper limit of normal) at screening, OR
- MRI positive for active, muscle inflammation within 12 weeks prior to screening, OR
- ... and 19 more (see full listing online)

Exclusion (29)

- Adequate pulmonary function, defined as saturated oxygen (SpO2 e 94%) on room air.
- Left ventricular ejection fraction (LVEF) e 30% as assessed by echocardiogram (ECHO) or multigated acquisition (MUGA) scan performed within 8 weeks prior to Screening.
- Participants must have the ability to comply with the requirements of the study.
- All participants of reproductive age/capacity will be required to use adequate contraception, defined as at least one form of a highly effective contraceptive (i.e., condoms, hormonal birth control, IUD), with any partners during the study period and for at least three months beyond the study period, for safety.
- Participant will have the ability to understand and provide written informed consent.
- ... and 24 more (see full listing online)

Locations (2 total)

Malcom Randall North Florida/South Georgia VA Medical Center, Gainesville, Florida, United States
Bioresearch Partner, Miami, Florida, United States