

The Pediatric Lupus Nephritis Mycophenolate Mofetil (PLUMM) Study

NCT05538208

Status	RECRUITING
Phase	Phase 2
Sponsor	Children's Hospital Medical Center, Cincinnati
Enrollment	105 participants

Key Eligibility Criteria

Inclusion (14)

- Inclusion
- Male or female aged 8 to < 21 years;
- Must meet Classification Criteria for SLE as per the criteria of the American College of Rheumatology (ACR)/ European League Against Rheumatism
- Diagnosed with proliferative LN as per the International Society of Nephrology/Renal Pathology Society⁴ based on kidney biopsy done within 90 days prior to enrollment into the study;
- Subjects may have been previously diagnosed with LN. For study inclusion, the kidney biopsy must be interpreted as one of the following classes: Class 3, Class 3/5, Class 4, or Class 4/5.

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

Exclusion (30)

- Perceived or stated inability to adhere to the study protocol;
- Hypersensitivity to MMF or any component of the drug product;
- Presence of features (from SLE or other chronic disease) that a-priori suggest that the subject benefits from other therapies than that suggested or allowable by the study protocol; These disease features include but are not limited to severe, progressive, or uncontrolled hepatic, hematologic, gastrointestinal, metabolic, endocrine, pulmonary, cardiac or neurologic disease.
- History of other kidney disease besides LN or prior to the diagnosis of SLE;
- Need for renal replacement therapy within 2 weeks from Baseline Subjects can have required short-term renal replacement therapy prior to Baseline, for example due to preceding acute kidney injury.

... and 25 more (see full listing online)

Locations (19 total)

University of California, San Francisco, San Francisco, California, United States

Children's Hospital Colorado, Aurora, Colorado, United States

Emory Children's Center, Atlanta, Georgia, United States

... and 16 more locations

<https://clinicaltrials.gov/study/NCT05538208>

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