Lupus Nexus Landmark Study: A Prospective Registry and Biorepository

Introduction

Systemic lupus erythematosus (SLE) is a debilitating autoimmune disease that disproportionally impacts women and minorities.

The cause of lupus is unknown, and no single laboratory test can definitively identify lupus.

Although there are numerous contributing factors to the lag in research discoveries and new treatments for lupus patients, limited access to standardized, high-quality biological samples and natural history data provides a significant roadblock to advance lupus research.

Objective

The purpose of the registry and biorepository is to provide a mechanism to store clinical data, linked biospecimens and molecular data to support the conduct of future research on SLE, including lupus nephritis (LN).
The study will be used to address research questions based on three categories

1. Historical: Focuses on genetic drivers and antigenic targets of SLE.
2. Cross-Sectional: Focuses on phenotypic and mechanistic heterogeneity in diverse SLE populations.
3. Longitudinal: Focuses on the mechanistic correlates for severity and outcome, including therapeutic responses.

Importance of Participation

This registry and biorepository is optimally positioned to drive science forward as an asset that can provide a game-changing contribution to lupus patient- centered research. The study aims to:

- Understand the underlying disease process.
- Understand lupus heterogeneity and link to clinical phenotypes.
- Identify potential drug targets from analysis of biomarkers.

SLE Cohorts & Inclusion Criteria

New Onset

New onset of SLE within 12 months of meeting classification criteria or physician diagnosis of SLE.

Lupus Nephritis Active

Renal biopsy confirming LN diagnosis within 4 months of enrollment showing class III or IV+/-V, class V, or class II. Or, for those with clinically suspected and active LN with intention to treat but unable to obtain a kidney biopsy, additional support from the treating physician must be submitted for review, including, but not limited to, the amount or degree of worsening proteinuria, documented active urinary sediment, and serological biomarkers.

Extra- Renal Lupus Flare

A flare within 30 days preceding enrollment into the study. Individual elements for specific flare definitions, such as Safety of Estrogens in Systemic Lupus Erythematosus National Assessment (SELENA)- Systemic Lupus Erythematosus Disease Activity (SLEDAI) Flare Index, will be collected at time of visit.

Prevalent Cases

Does not meet inclusion criteria for any of the other three cohorts at entry, and negative for flare at entry.

Laboratory Research Data

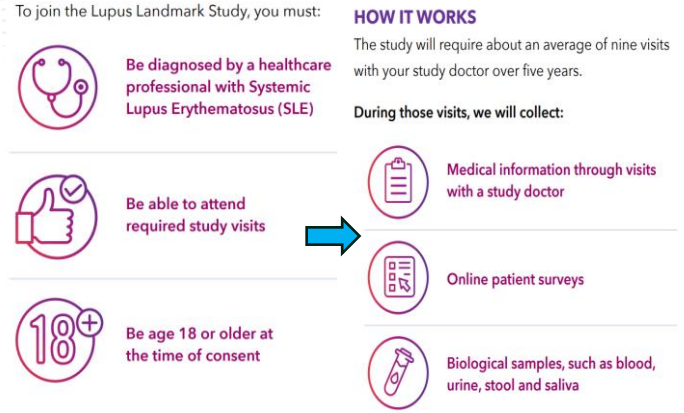
Biospecimens collected from participants may be analyzed on a variety of research platforms, which may include the following:

Circulating Biomarkers- Using serum, plasma, urine, or saliva.

Whole Genome Sequencing
Genomic Analysis
Immunotyping

Cerebrospinal fluid
Synovium Fluid/ Knee Biopsy
Bone Marrow Biopsy
Kidney Biopsy

Study Requirements



Enrollment at UMass

The study-wide target enrollment is 3,500 patients after 5 years.

At UMass Chan we plan to enroll 115 participants over 5 years.

Our Statistics as of May 2024

Total: 10 Participants

New Onset: 20 %
LN Active: 10%
Extra- Renal Lupus Flare: 0 %
Prevalent Cases: 70 %

UMass Chan MEDICAL SCHOOL

Advancing together

LUPUS RESEARCH ALLIANCE Breaking through.

Lupus THERAPEUTICS an affiliate of LUPUS RESEARCH ALLIANCE