

Full Title SLICE: Sex based differences in the immunobiology and natural history of acute and convalescent Lyme disease

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Study Objectives

To examine sex-based differences in immune response and clinical outcomes in participants with Lyme disease

To compare host humeral and cellular immune response variability between men and women

To examine the relationship of immune response, inflammatory signally proteins, and the human microbiome over to time to the development of Post-treatment Lyme disease syndrome (PTLDS)

To examine differences in the coping mechanism, psychological susceptibility to the development of persistent symptoms and decreased daily life functioning in women vs. men after treatment of Lyme disease

To develop a biorepository of specimens for future investigations, including biomarker testing, assay development, and the identification of biological risk factors

Inclusion Criteria

Patients are eligible to be included in the study if they meet all of the following criteria:

- Adults participants \geq 18 years of age
- Acute, untreated Lyme disease meeting case criteria of CDC
- Participants will have no more than 72 hours of treatment for the current episode of Lyme disease at the time of enrollment
- Participants will have physician-documented erythema migrans $>$ 5 cm

- Duration of symptoms cannot be greater than 3 months at the time of enrollment

**Exclusion
Criteria**

Patients are excluded if they meet any of the following criteria:

- Participants who are pregnant
- Participants with a previous diagnosis of Lyme disease
- Participants with a significant intolerance or allergy to doxycycline
- Participants with a history of illicit drug or substance abuse
- Participants with a major immunosuppressive illness or medications or pre-existing medical disorders likely to be associated with prolonged fatigue or pain or neurocognitive symptoms such as prior history of fibromyalgia, chronic fatigue syndrome, or delusional psychiatric disorder will be excluded from the study

**Affiliations &
Sponsors**

Johns Hopkins Clinical Research Network

Status

Open to enrollment

Keywords

Lyme, erythema migrans