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Pregnancy & Early Neurodevelopmental Outcomes Following In Utero Lyme Disease Exposure

Dr. Sarah Mulkey, MD, PhD | May 3, 2023
Prenatal Pediatrics Institute, Children's National Hospital

Outline

- Introduction
- Study Details
- Partner With Us!
- Questions

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Introduction

Study Team

Sarah Mulkey
MD, PhD (she/her)

Prenatal and Neonatal Neurologist, Division of Prenatal Pediatrics

Co-Director, Congenital Infection Program

Roberta DeBiasi
MD, MS (she/her)

Chief, Division of Pediatric Infectious Diseases

Co-Director, Congenital Infection Program

Meagan Williams
MSPH, CCRC (she/her)

Clinical Research Coordinator, Divisions of Pediatric Infectious Diseases and Prenatal Pediatrics

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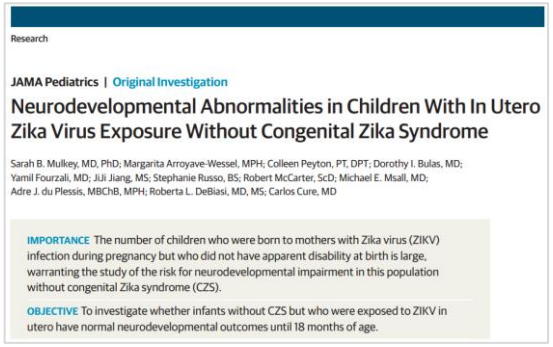
Above: Children's National Hospital, Washington, DC

Congenital Infection Program

The Congenital Infection Program specializes in evaluating and researching outcomes of children with antenatal exposure to infectious agents.



Top left image: NPR article highlighting the Congenital Infection Program team

Bottom left image: Publication by Mulkey et al. in JAMA Pediatrics (2020)

Right image: Congenital Infection Program website

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Lyme Disease and Pregnancy

There is some scientific agreement that *B. burgdorferi* can be vertically transmitted to a developing fetus and may cause congenital infection.

However, to date, no studies have systematically investigated pregnancy and long-term child neurodevelopment outcomes following in utero exposure to *B. burgdorferi*.

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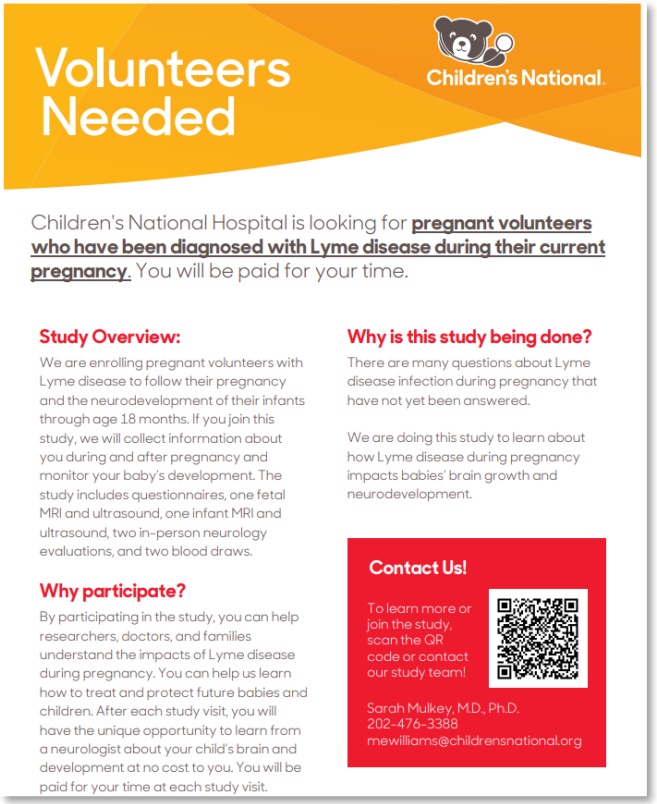
New Study: Now Recruiting!

We are conducting a pilot study to assess feasibility of evaluating **outcomes of pregnancies affected by Lyme disease infection** and the brain development of **fetuses and children who were exposed to Lyme disease in utero**.



Volunteers Needed

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Children's National Hospital is looking for **pregnant volunteers who have been diagnosed with Lyme disease during their current pregnancy.** You will be paid for your time.

Study Overview:

We are enrolling pregnant volunteers with Lyme disease to follow their pregnancy and the neurodevelopment of their infants through age 18 months. If you join this study, we will collect information about you during and after pregnancy and monitor your baby's development. The study includes questionnaires, one fetal MRI and ultrasound, one infant MRI and ultrasound, two in-person neurology evaluations, and two blood draws.

Why participate?

By participating in the study, you can help researchers, doctors, and families understand the impacts of Lyme disease during pregnancy. You can help us learn how to treat and protect future babies and children. After each study visit, you will have the unique opportunity to learn from a neurologist about your child's brain and development at no cost to you. You will be paid for your time at each study visit.

Why is this study being done?

There are many questions about Lyme disease infection during pregnancy that have not yet been answered.

We are doing this study to learn about how Lyme disease during pregnancy impacts babies' brain growth and neurodevelopment.

Contact Us!

To learn more or join the study, scan the QR code or contact our study team!

Sarah Mulkey, M.D., Ph.D.
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$$$ Funding for this project was provided by a grant from the Clinical Trials Network supported by the Steven and Alexandra Cohen Foundation.

Study Details

Overview

We will recruit participants with Lyme disease or Post-Treatment Lyme Disease Syndrome **during pregnancy** and follow their infants' development **through 18 months** of age.

This pilot study will be the first study to evaluate the long-term impact of Lyme disease exposure on pregnancy, brain development, and childhood neurodevelopment.

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Study Aims

Assess child neurodevelopment

1

To determine whether infants exposed to *B. burgdorferi* in utero have abnormal neuro-developmental outcomes to age 18 months

Evaluate brain abnormalities

2

To evaluate whether there are abnormalities in the fetal and neonatal brains of *B. burgdorferi*-exposed fetuses and infants

Assess pregnancy outcomes

3

To assess pregnancy outcomes associated with gestational exposure to Lyme disease based on the timing of Lyme disease exposure, symptom onset, and treatment

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Participants

- **All** participants must be pregnant, >18 years of age, capable of comprehending the study, and available for long-term follow-up requirements*

* Note: Travel to Children's National Hospital for a fetal and infant MRI is strongly preferred, but not required. Participants will be excluded from the MRI portion of the study if they have health issues or metallic implant that precludes them from undergoing MRI.

Cohort #1: Lyme disease diagnosis during pregnancy

Cohort #2: Post-Treatment Lyme Disease Syndrome during pregnancy

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Two Cohorts

Cohort #1:
Lyme disease diagnosis during pregnancy

About Cohort #1:

- Currently **pregnant**
- Meet CDC criteria for clinical/ laboratory diagnosis of any stage of **Lyme disease occurring during any trimester of current pregnancy**

Cohort #2:
Post-Treatment Lyme Disease Syndrome during pregnancy

About Cohort #2:

- Currently **pregnant**
- **Completed treatment for any stage of Lyme disease between 6 months and 3 years ago**
  - Lyme disease previously diagnosed using CDC criteria for clinical/laboratory diagnosis
- Currently with **active symptoms** attributed to clinician-diagnosed Post-Treatment Lyme Disease Syndrome (PTLDS) or Chronic Lyme

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Study Timeline

 **Pregnancy** (enrollment + one in-person visit, optional qualitative interview)

 **Delivery** (data sharing with birth hospital, placental pathology)

 **Infancy** (two in-person visits, three online visits)

Ongoing: Monitoring of clinical and demographic factors that may impact outcomes (Lyme/PTLDS, medical history, mental health, nutrition, SES, etc.)

Schedule of Events: Pregnancy

PREGNANCY

MRI and ultrasound (2^{nd} or 3^{rd} trimester)

Antibody testing and cytokine panel

Monitoring of Lyme/ PTLDS, pregnancy, and fetal growth

Optional: Qualitative interview

DELIVERY

Delivery hospital shares:

- newborn records, including infant length and weight
- labor and delivery records
- placental pathology reports

Additional analysis of placenta

INFANCY

Infant brain MRI, cranial ultrasound, neurological exams

Antibody testing and cytokine panel

Ongoing monitoring of infant growth and neurodevelopment (ASQ, WIDEA, AIMS)

ONGOING: Monitoring of clinical and demographic factors that may impact outcomes (SES, nutrition, medical history, Lyme/PTLDS history, mental health, etc.)

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Schedule of Events: Delivery

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Partner With Us!

We Need Your Help!

If you…

- know a pregnant person who might be eligible to participate in this study
- have colleagues whose clients might be pregnant with Lyme disease or PTLDS
- are interested in sharing this research with your organization's audience or stakeholders

Please refer them to our research team!

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If you have patients who may be eligible, please contact us!

Sarah Mulkey, MD, PhD (PI):
sbmulkey@childrensnational.org

Research team:
Meagan Williams, MSPH:
mewilliams@childrensnational.org
cnhlymestudy@gmail.com

Tip: Take a photo of this slide to reference later!

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Recruitment Toolkit

If you are interested in helping our team find study participants, we made you a **Recruitment Toolkit**!

The Toolkit includes our study recruitment flyer, social media templates, important links, FAQs, and more to help you share information about our study with your patients, clients, and colleagues!

Link on the next slide →

Stay Connected

Scan the QR code or visit the website below to stay connected with our research team!

http://eepurl.com/ipNdhl

Make sure to select "**Yes**" if you want access to our Recruitment Toolkit!

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Questions?

- **Email the team**: cnhlymestudy@gmail.com
- **Stay connected**: Scan the QR code to sign up for our email newsletter!
- **Thank you to our funders!** This study was funded by a grant from the Clinical Trials Network supported by the Steven and Alexandra Cohen Foundation.