



Lyme Meningitis Study

With more than 300,000 new cases of Lyme disease each year in the U.S., approximately half of new cases occur in children. Children with Lyme meningitis usually have a headache, fever and fatigue. Children diagnosed with Lyme meningitis are treated with either oral or intravenous antibiotics.

We are conducting a study to evaluate 2 things:

1. Compare the two medications usually used to treat Lyme Meningitis to determine if one has better outcomes or is more manageable for families.
2. Determine patient, parent and clinician preferences for the treatment of Lyme meningitis to inform future decision-making

To do this, we will be enrolling 250 children at 20 U.S. medical centers where Lyme disease is endemic. Treatment decisions will be made by you and your child's medical team. **This study will not affect in any way how you/your child are treated for Lyme meningitis. We seek simply to learn how quickly your treatment works for you.** You may be in this study if you:

- ✓ Are between 1 and 21 years old
- ✓ Have been recently diagnosed with Lyme Meningitis
- ✓ Treatment plan includes oral doxycycline or IV ceftriaxone/cefotaxime

If you decide to join this research study, we will collect the following information:

- Current symptoms and treatment preferences
- Daily symptoms until improved (30 days maximum)
- Phone interview at 6 weeks
- If your child has peripheral facial palsy, weekly facial photos until resolution

If you are discharged today, without knowing all of your test results, you may be called within the next week to provide verbal consent for the study and to begin the above study procedures.

Participation in this study will not benefit you directly. Participation will inform the best treatment for children with Lyme meningitis in the future. It will take you about 6 months to complete this study. The most likely risk is accidental disclosure of confidential medical information. Many measures have been taken to prevent this risk.

Your clinical care will be covered by your health insurer as your treatment will not change by taking part in this research. **You will receive between \$50 and \$110 in gift cards for the completion of study activities.**

If you have any questions about this study, please contact the Principal Investigator at Boston Children's Hospital by calling: (###) ###-#### or Email: LymeMeningitis@childrens.harvard.edu.

