Columbia University Research Projects & Columbia Specimen Bank

The Lyme & Tick-Borne Diseases Research Center at Columbia University Medical Center was formed in 2007 by the Lyme Disease Association, Inc. and then Time for Lyme (GLA) in partnership with the Columbia University Board of Trustees. The endowed center was the first of its kind set up to investigate chronic disease. Since that time, many studies have been carried out and published through the Center.

Currently, the Center is looking for research subjects for 3 studies:

Reducing Chronic Pain in Post-Treatment Lyme Syndrome: a Brain Imaging and Treatment Study

Finding Better Tests and Markers for Lyme Disease: a Study for Patients with Newly Diagnosed Lyme Disease

Meditation & Kundalini Yoga Breathing – Do these help to reduce pain & fatigue in patients with chronic lyme disease?

Go to http://columbia-lyme.org/research/cr_research.html for details.

Additionally, Columbia has a Specimen Resource Repository housed at Columbia which the LDA contributed funds to that is "committed to serve as a resource for serum and spinal fluid specimens that can be accessed for study both by researchers at Columbia and by researchers throughout the world…. brain, spinal cord, and other tissues from people who have had Lyme disease at some time in their life are collected for current and future investigation at the NYS Psychiatric Institute. People with a history of well-documented Lyme disease, which must include a positive Lyme blood test, should contact us

[Columbia] at 646-774-7503. It is most important that your next of kin or other individual who will be responsible for arrangements after your death be made aware of your wishes, provided with the Columbia Lyme Center contact information, and be informed that they should contact us immediately after your death. Putting aside in a safe place your medical history and laboratory tests is very important as this information is necessary to review before we can conduct the post-mortem investigation. In the event that death has just occurred or is imminent, time is of the essence. If this is the case, please call this emergency number 646-549-8880.

Go to http://columbia-lyme.org/research/columbia_specimen_bank.html for details.

Advanced Laboratory Services Borrelia Test Eval

A Multicenter Study to Evaluate a Borrelia Diagnostic Test in Subjects With Early Stage or Late Stage Lyme Disease

This study is currently recruiting participants.
Verified July 2016 by Advanced Laboratory Services, Inc.

Please refer to this study by its ClinicalTrials.gov identifier: NCT02741609

https://clinicaltrials.gov/ct2/show/study/NCT02741609

Purpose

This study will evaluate Advanced Laboratory Services Borrelia diagnostic test by culturing Borrelia spirochetes from human serum in subjects with early or late Lyme

disease.

This is an 8 month study. Subjects entering the study will have two blood samples collected one month apart if they have early Lyme disease and one blood sample collected if they have late Lyme disease. Subjects who sign an IRB-approved consent form and meet the inclusion and exclusion criteria will be entered into the study. Subjects will be assigned a subject number upon entry and this number will be retained throughout the study.

Study Type:	Interventional
Study Design:	Intervention Model: Single Group Assignment Masking: Open Label Primary Purpose: Diagnostic
Official Title:	A Multicenter Study to Evaluate a Borrelia Diagnostic Test in Subjects With Early Stage or Late Stage Lyme Disease

Further study details as provided by Advanced Laboratory Services, Inc.:

Primary Outcome Measures:

- Diagnostic accuracy of the Advanced Laboratory Services, Inc. (ALSI) Borrelia Diagnostic Test (BDT) culture, for positive and negative predictive value, as compared to conventional microbiological methods. [Time Frame: Baseline to 16 weeks] [Designated as safety issue: No]

Secondary Outcome Measures:

- Diagnostic accuracy of ALSI culture for early-onset presentation of Lyme disease, as measured by positive and negative predictive value. [Time Frame: Baseline to 16 weeks] [Designated as safety issue: No]
- Diagnostic accuracy of ALSI culture for late-onset presentation of Lyme disease, as measured by positive and negative predictive value. [Time Frame: Baseline to 16 weeks] [Designated as safety issue: No]

Estimated Enrollment:	300

Study Start Date:	April 2016
Estimated Study Completion Date:	May 2017
Estimated Primary Completion Date:	April 2017 (Final data collection date for primary outcome measure)

Eligibility

Ages Eligible for Study:	18 Years and older (Adult, Senior)
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria
Inclusion Criteria:

1. Subject must provide written informed consent prior to the conduct of any study-related procedures.
2. Male or female subjects who are at least 18 years of age.
3. Have early Lyme disease based on the following criteria: Signs, symptoms and clinical history consistent with early stage Lyme disease. Subjects must have a physician-diagnosed erythema migrans (EM) rash and should have systemic symptoms indicative of disseminated infection. Symptoms may include fever, headache, fatigue, myalgias, arthralgias, and stiff neck. Paired acute and convalescent titers will be drawn (first draw at time of initial visit and second draw 4 weeks later) or,
4. Have late Lyme disease based on the following criteria: Signs, symptoms and clinical history consistent with late stage Lyme disease, including but not limited to disseminated rash, arthritis, meningitis, facial palsy, or carditis.
5. Subjects must be willing and have the ability to safely have the required quantity of blood drawn for the study at the discretion of the investigator.
6. Subjects must have blood samples freshly collected (no supplemental frozen samples) and the samples must reach ALSI’s laboratory on a weekday and within 24 hours of being drawn.

Exclusion Criteria:

1. Early Lyme disease: Subjects without an EM rash or do not have symptoms recognized as being associated with Lyme disease.
2. Exposure to antibiotics of any type during the 6 weeks prior to the initial blood sample collection.
3. Immune deficiency significant enough to render serological tests less reliable.
4. The subject is unwilling or unable to safely have the required quantity of blood drawn for this study.
5. Subjects who are not able to understand all of the requirements of the study or unable to give informed consent and/or comply with all aspects of the evaluation.
6. Subjects that have any other condition or situation which, in the opinion of the investigator, would make the subject unsuitable for enrollment or could interfere with the subject participating in and completing the study.
7. Subjects that have undergone testing for Lyme disease within the past year.
8. Subjects that have a prior diagnosis of Lyme disease.

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Contacts

Contact: Phyllis A Mast, MA	484-494-5157	pmast@innovative-cro.com	

Locations

United States, Delaware	
Delaware Integrative Medicine	Recruiting
Georgetown, Delaware, United States, 19947	
Contact: Henry Childers IV, MD 302-258-8853	

United States, Maine	
Penobscot Bay Medical Center	Recruiting
Rockport, Maine, United States, 04956	
Contact: Mark Eggena, MD 207-593-5800	
United States, Maryland	
IRC Clinics, Inc.	Recruiting
Towson, Maryland, United States, 21204	
Contact: Amanda Hazelton	
Principal Investigator: Alberto Yataco, MD	
United States, Pennsylvania	
Detweiler Family Medicine & Associates, PC	Recruiting
Lansdale, Pennsylvania, United States, 19446	
Contact: Jennifer Adams, LPN	
Principal Investigator: Evan Kessler, DO	
Suburban Research Associates	Recruiting
Media, Pennsylvania, United States, 19063	
Contact: Avrom Brown, MD	
United States, Rhode Island	
Lyme Center of New England	Recruiting
Cumberland, Rhode Island, United States, 02864	
Contact: Susan Neuber, NP 401-334-5963	
The Miriam Hospital of Infectious Diseases	Recruiting
Providence, Rhode Island, United States, 02906	
Contact: Rebecca Reece, MD	
Contact: Timothy Flanigan, MD	
United States, Virginia	
Virginia Center for Health & Wellness	Recruiting
Aldie, Virginia, United States, 20105	

Contact: Andrew Heyman, MD 703-327-2434	
Cardinal Internal Medicine	Recruiting
Woodbridge, Virginia, United States, 22192	
Contact: Atoussa Farough, MD 703-897-4700	

Sponsors and Collaborators

Advanced Laboratory Services, Inc.

Investigators

Principal Investigator:	Timothy R Schwartz, PhD	Advanced Laboratory Services

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https://clinicaltrials.gov/ct2/show/study/NCT02741609

New Columbia Lyme Treatment Study to Reduce Pain

Reducing Chronic Pain in Post-Treatment Lyme Syndrome: a Brain Imaging and Treatment Study

Background: At least 5-15% of patients with Lyme disease (7,500-45,000 new cases a year) develop Post-treatment Lyme Syndrome (PTLS) – debilitating residual symptoms that last months to years, even after having received antibiotic treatment. Often patients with PTLS experience chronic pain in their muscles or joints or nerves.

Do patients with PTLS benefit from treatment with a medicine that reduces central

pain? Because many PTLS patients have pain that persists despite antibiotics and because we know that medicines which modulate the pain pathways in the brain can help to reduce or eliminate pain, we plan to treat patients with a medicine that is FDA approved for the treatment of pain. This medicine is known as Milnacipran (the trade name is "Savella"); this medicine is not addictive and it has been shown to reduce chronic pain by its multiple actions on pain pathways. All patients in the study will be treated with this FDA approved medicine.

Second, we wish to test whether the pain can be improved even further by adding a medicine which is known to modulate the glutamate transmission involved with pain in the brain. **This medicine – D-Cycloserine – is actually an antibiotic, currently FDA approved for the treatment of tuberculosis. Because of its action on glutamate receptors, we are hypothesizing that it will help to decrease pain even further in patients with Lyme-related pain.** In order to test this hypothesis, after 6 weeks of being on Milnacipran, all patients will then be given an additional treatment – either D-Cycloserine or a placebo pill (a placebo is a pill that does not contain any active medication.) At the end of 12 weeks, we will then evaluate improvement compared to when the patient started in the study using the same clinical and neuroimaging (fMRI) tests.

Finally, we want to know whether patients with PTLS have over-active central pain circuits in the brain. Because pain is processed through the brain's pain circuits, we wish to examine whether people suffering from PTLS have hyper-active pain circuits that make them more sensitive to pain than those who have normally-active pain circuits. To do this, we will be comparing patients with PTLS to healthy volunteers by conducting careful neurologic and brain imaging (fMRI) studies.

We hope that this study will provide valuable information about how the brain processes pain signals in PTLS and about whether this treatment approach is effective.

If you are between 18 and 55 years old, have been treated for Lyme disease, and have developed persistent pain post Lyme Infection, you may be eligible!

This study will take place at Columbia University Medical Center: 1051 Riverside Drive, New York, NY. **Please contact Ellen Brown at 646-774-8100 or eb3048@cumc.columbia.edu for an initial screening**. If you are eligible, all study related procedures and treatment will be conducted at no financial cost to you

ENROLLMENT START DATE: Feb 2016