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