LDN FIBROMYALGIA STUDY

Stanford's Clinical Trial of Naltrexone Recruiting Patients

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Low dose naltrexone is a prescription drug used off label for MS and other medical conditions. Subjects are needed for the first clinical trial of LDN in fibromyalgia.

Fibromyalgia Study

Investigators at Stanford University are recruiting patients with fibromyalgia living in the Stanford area for a clinical trial. The study is being conducted by Dr. Jarred Younger and his colleagues at the Stanford Packard Center for Translational Research in Medicine. In this double blind, placebo-controlled clinical trial, researchers are evaluating the effects of low dose naltrexone (LDN) in the autoimmune disorder fibromyalgia.

Fibromyalgia and its Symptoms and Causes

Fibromyalgia was defined by Dr. Frederick, the Director of the National Databank for Rheumatic Diseases in a 1990 paper that first defined fibromyalgia's diagnostic guidelines.

Fibromyalgia is a musculoskeletal disorder characterized by widespread pain in muscles, tendons, and ligaments and pain upon pressure of specific trigger points in the back of the head, upper back and neck, upper chest, elbows, hips and knees. Pain in fibromyalgia may be accompanied by stiffness as well as sleep disturbances, fatigue, headaches, and heightened sensitivity to odors, lights, and other sensations. In addition, patients with fibromyalgia frequently have symptoms of irritable bowel syndrome (IBS).

Causes of Fibromyalgia

The causes of fibromyalgia are unknown. However, brain scans of people with fibromyalgia have confirmed what patients already know: Their pain is real and occurs primarily because their threshold for tolerating pain impulses is substantially lower than that of most individuals. However, the mechanism causing this lowered pain threshold is unknown.

Current thinking is based on a theory called "central sensitization." This theory states that people with fibromyalgia have a lower threshold for pain related to increased sensitivity of their brain cells to pain signals. Researchers believe repeated nerve stimulation causes specific cellular changes in the brains of people with fibromyalgia resulting in abnormal increase in levels of certain nervous system chemicals known as neurotransmitters that signal pain.
Suspected triggers of fibromyalgia include chronic sleep disturbances, injury or trauma, infections, sympathetic nervous system abnormalities, alterations in muscle metabolism and blood flow, psychological stress, and hormonal changes. Several studies show an increased incidence of hypothyroidism in patients with fibromyalgia.

**LDN Study Goals**

Dr. Younger is a Postdoctoral Research Fellow in Stanford's Translational Medicine Program studying opioid systems in patients with chronic pain. His approach is to investigate these difficult chronic pain problems with pharmacological, psychological, neuroimaging, physiological, and genetic perspectives. He is particularly interested in the role opioid-peptides and opiate antagonists such as naltrexone play in complex pain disorders.

The Stanford Fibromyalgia Clinical Trial, which is being funded by the American Fibromyalgia Syndrome Association as well as private gifts, is the first clinical trial to evaluate the safety and efficacy of LDN in fibromyalgia. Employing a series of imaging tests, laboratory tests, and Quality of Life surveys, Dr. Younger will evaluate patients using LDN and patients receiving a placebo over a three-month period. The primary study outcomes are on pain, fatigue, and sleep quality. Secondary outcomes involve mechanical and thermal pain sensitivity.

**Translational Medicine**

In translational medicine, researchers apply scientific findings in genetics, microbiology, biochemistry and related disciplines to patient care. The focus is on the outcome of specific patient populations to treatments and therapies that have been found to work in laboratory research studies. In other words, this branch of medicine takes the bench to the bedside by evaluating how the theories and findings of the research lab apply to patient care and treatment.

**Eligibility Requirements**

Because patients are required to have biomedical tests every two weeks, for 3 months, it's essential that they live in the San Francisco Bay/Palo Alto area or are within easy commuting distance from Stanford University. Subjects must be 18-65 years of age and suffering from moderate to severe fibromyalgia. Patients must also not be taking opioid analgesics, and they must not be pregnant or plan on becoming pregnant. Healthy volunteers free from fibromyalgia are also needed to serve as controls. Subjects cannot have known allergies to naloxone or naltrexone.

**Contact Information**

Further information on the study, a participant questionnaire, a brochure describing the study, and contact information are available at the Stanford Fibromyalgia Trials webpage.
Resources:

Dr. Jarred Younger, Stanford University College of Medicine, Private Communication, January 2008.


Mayo Clinic on Fibromyalgia accessed Feb 1, 2008.

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