

-- NIH funded clinical trial -- ALS with antibiotics

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<http://www.clinicaltrials.gov/ct/gui/show/NCT00047723?order=2>

This study is currently recruiting patients.

Purpose --

The purpose of this trial is to test the safety, tolerability, and effectiveness of minocycline compared to placebo in patients with amyotrophic lateral sclerosis (ALS).

Amyotrophic Lateral Sclerosis

Drug: minocycline

Phase III

Study Type: Interventional

Study Design: Treatment, Randomized, Double-Blind, Placebo Control

Further Study Details:

Expected Total Enrollment: 400

Study start: January 2003

ALS is a progressive neurodegenerative disorder without cure or known treatment that significantly improves function. Loss of motor neurons in the brain and spinal cord of ALS patients causes the progressive symptoms. Laboratory studies have linked inducible nitric oxide synthase (iNOS) and caspase enzyme activation to motor nerve cell death in ALS. Minocycline—a medication currently approved by the FDA for treatment of bacterial infections—is a tetracycline antibiotic with high central nervous system penetration when taken orally. The drug inhibits the activity of iNOS and caspase enzymes.

Minocycline has been tested and shown to protect nerve cells in many scientific experiments. It reduces cell death and prolongs survival in animal models of ALS, stroke, trauma, Huntington's disease, and Parkinson's disease. It has been shown to be beneficial in many different animal experiments of ALS, conducted in Europe, Canada and

the United States.

Minocycline has been tested in 2 preliminary human trials and has been shown to be safe in patients with ALS. It has been well tolerated in conjunction with riluzole (Rilutek), the only currently FDA-approved medication for ALS.

This trial is the final important step in determining whether minocycline improves the course of ALS. The principle objective of this clinical trial is to determine whether minocycline slows disease progression and helps maintain function in patients with ALS. This multi-center placebo-controlled study will select patients early in the course of ALS, when a neuroprotective therapy may be most beneficial. The study will measure change in function (as detected by ALSFRS-R scores), strength, pulmonary function, survival, and quality of life. Participants will undergo monthly outpatient evaluations and analysis of laboratory and adverse events. This is a 13-month study.