

Title: **Clinical Trial of Ceftriaxone in Subjects With Amyotrophic Lateral Sclerosis (ALS)**
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This trial is **currently enrolling** patients.

Primary Outcome Measures:

- Survival
- ALSFRS-R

Secondary Outcome Measures:

- vital capacity
- evaluation of multiple upper extremity muscles using hand held dynamometry
- quality of life
- long-term safety and tolerability of ceftriaxone

Estimated Enrollment: 600

Study Start Date: July 2006

Estimated Study Completion Date: June 2012

Estimated Primary Completion Date: June 2012 (Final data collection date for primary outcome measure)

Detailed Description:

It is known that nerve cells called motor neurons die in the brains and spinal cords of people with amyotrophic lateral sclerosis (ALS). However, the cause of this cell death is unknown.

Researchers think that increased levels of a chemical called "glutamate" may be related to the cell death. For this reason researchers want to study drugs that decrease glutamate levels near nerves. Ceftriaxone—a semi-synthetic, third generation cephalosporin antibiotic—may increase the level of a protein that decreases glutamate levels near nerves. Studies of ceftriaxone in the laboratory suggest that it may protect motor neurons from injury.

Ceftriaxone is approved by the U.S. Food and Drug Administration (FDA) for treating bacterial infections but not for treating ALS. Also, ceftriaxone has not been given to people over a long period of time, such as months or years. The goals of this study are to evaluate the safety and effectiveness of ceftriaxone as a treatment for ALS, and to determine the safety and effectiveness of long-term use of the drug in people with ALS.

A total of 600 eligible people with ALS will be enrolled in this multi-center research study. Participants will be randomly assigned to receive treatment with ceftriaxone (2/3 of participants) or placebo (1/3 of participants) for at least 12 months.

The study consists of three stages. The first stage, which has completed enrollment, will look at whether ceftriaxone enters the cerebrospinal fluid (the fluid that surrounds the spinal cord, also called CSF) in amounts that are high enough to be of possible benefit. The second stage, which

has also completed enrollment, will look at the safety and side effects of the study drug when taken daily for at least 20 weeks. The study is currently enrolling subjects for the third stage, which began in Spring 2009, and will determine whether the study drug prolongs survival and slows decline in function due to ALS.

Eligibility:

Ages Eligible for Study: 18 Years and older

Genders Eligible for Study: Both

Accepts Healthy Volunteers: No

Criteria

This is a partial list. Please check with the nearest site to review the full eligibility criteria.

Inclusion Criteria:

- Participants will be people with ALS, at least 18 years of age.
- Participants must be medically able to undergo the study procedures and have a caregiver or other individual who will be available to help with daily study medication administration.
- Participants should live within a reasonable distance of the study site, due to frequent study visits.

Exclusion Criteria:

- Participants cannot be taking any other experimental medications for ALS, or have a history of sensitivity to cephalosporin antibiotics (such as Ancef, Keflex, Ceclor, Ceftin, Lorabid, Suprax, or Fortaz).

Locations:

Please visit the NEALS Website for a complete list of site locations -

http://www.alsconsortium.org/nealsclinicalresearch_Ceftriaxone.html

Location information is also available on the clinicaltrials.gov website -

<http://www.clinicaltrials.gov/ct2/show/NCT00349622?term=ALS+Ceftriaxone&rank=1>