Clinical Trial of Ceftriaxone in Subjects with ALS

Information for Potential Research Participants

This study is Coordinated by the Neurology Clinical Trials Unit at Massachusetts General Hospital Boston, Massachusetts

Funding for this study is provided by The National Institutes of Health (NIH)

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Coordinating Center
Massachusetts General Hospital
Boston, MA

(Version 3.0 March 5, 2009)

For More Information

Thank you for your interest in the Clinical Trial of Ceftriaxone in Subjects with ALS.

If you have more questions, or are interested in participating in this research study, please contact the study coordinator,

Stacey Masse, R.N..

By phone: 313-745-6124

By email: smasse@med.wayne.edu
What procedures will I have done if I decide to enroll in the study?
You will come to the study site for regular study visits. At these visits, a variety of procedures will be performed, including:
- Blood draws and urine collection for safety studies
- Strength testing of your arms and legs
- Vital capacity (breathing) testing
- Every few months, you will be asked questions about your daily activities and quality of life.
Please ask the study coordinator at your ALS Clinic to explain all of the procedures involved in the study.

How often will I need to come to the study site for visits?
For the first several weeks, it will be necessary to come to the site every week or two. After that, you will return to the study site every 4 weeks until the end of the study.

How long will I be in the study?
The length of time it takes you to complete the study will depend upon when you started the study. The study will end when the last participant reaches 52 weeks of treatment. Therefore, the shortest time to complete the study will be 52 weeks.

Is there a chance that I will get a placebo?
Yes. This is a double-blind, placebo-controlled study. This means that neither you nor the study staff will know who is receiving ceftriaxone and who is not. There are 2 groups in the study. You have a 2 in 3 chance of receiving ceftriaxone and a 1 in 3 chance of receiving placebo (substance that looks like the study drug but contains no active medication). This assignment will be entirely random.

How will the study medication be given?
Because ceftriaxone is an intravenous (IV) medication, participants will also have an intravenous line (called a central venous catheter) placed in a vein on the right side of your chest. The study medication will be given through this catheter. This type of catheter, called a “Hickman” catheter, is commonly used to administer medication into the veins.

Before you have the catheter placed, you and your caregiver will be trained at the study site to care for the catheter at home and to give the study medication through the catheter.

What are the risks of the study?
The risks of taking ceftriaxone for more than 4 to 6 weeks are not completely known. Taking ceftriaxone for more than 6 weeks may increase your risk of kidney or gall bladder problems. We will test your blood and urine frequently to check for signs of kidney problems, and you will have frequent abdominal ultrasounds to check for gall bladder problems.

Since ceftriaxone has not been tested in people with ALS, other unexpected side effects may occur.

What are the benefits of the study?
At this time it is not known if the study drug will provide any benefit to you. It is hoped that ceftriaxone will slow the rate of progression of ALS. The knowledge gained from this study may be of future benefit to you and others with ALS.