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, Meraida Polak.

By phone: 404.778.3807
By email: mpolak@emory.edu
Questions about the Ceftriaxone in ALS study

What is the purpose of the study?
The purpose is to evaluate the safety and effect of intravenous (IV) ceftriaxone treatment in amyotrophic lateral sclerosis (ALS).

What is Ceftriaxone, and why study it in ALS?
Ceftriaxone is an antibiotic (in a class known as “cephalosporins”) that is approved to treat certain types of infections.

The investigators involved in this study are interested in studying ceftriaxone because several studies of ceftriaxone in the laboratory suggest that it may protect motor neurons from injury.

What are some of the things necessary for me to be in the study?
• Your ALS symptoms began no more than 3 years ago
• Your Vital Capacity (breathing) must be at least 60% of normal
• You have someone (a caregiver or other person) who is available on a daily basis (twice a day) to help you take the study medication.
• You can not take part in the study if you are pregnant, are allergic to penicillin or other antibiotics of the same type as the study medication, or have a history of another neurological disorder (other than ALS).
• Please ask the study coordinator at your ALS clinic for a full list of the requirements.

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 your 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.