

A Phase II Controlled Trial of Human Allogeneic Umbilical Cord-Derived Mesenchymal Stem Cells (MSCs) for the Treatment of Refractory Lupus

Study Overview

Do you have active lupus that is not responding to your current medications?

If so, you may be eligible to participate in a clinical trial testing whether a novel stem cell therapy is effective in treating active lupus.

What is the treatment? The treatment consists of mesenchymal stem/stromal cells (**MSCs**) that come from umbilical cords. The cells are made at the Clean Cell Facility at the Medical University of South Carolina. It is believed these cells can correct some of the immune system problems that cause lupus. In this study, 2 out of 3 participants will receive one of two doses of stem cells, while 1 out of 3 will receive placebo (i.e. no cells). The treatment is a one-time infusion that takes approximately half an hour. Hundreds of patients have safely received these cells for a variety of other diseases. This trial is approved by the FDA and the Institutional Review Boards. Funding for this trial comes from the Lupus Foundation of America and the National Institutes of Health.

What are the criteria for participating? The criteria for entering the trial requires that your lupus be moderately active as judged by your rheumatologist despite your being on immunosuppressive therapy. These immunosuppressive therapies can include medications such as azathioprine (Imuran), leflunomide (Arava), methotrexate (Rheumatrex) and mycophenolate (Cellcept) among others. If you are receiving Benlysta or Rituxan, you will have to stop these drugs prior to entering the study.

How many study visits are there? There are **12 study visits over 1 year** to allow the study doctors to assess how you are doing. All participants will continue the medications they were on at the time they enter the trial.

Safety is the most important consideration in this trial. You and your doctor can at any time change your medications if it is felt the activity of your lupus warrants a change.

Will I be charged for the study treatment? There is no charge for the study treatment, lab tests or evaluations and compensation is provided to help offset costs related to your time and travel.

How do I learn More? You can contact the MiSLE study coordinator, **Stephanie Dezzutti** by phone at 843-792-8997 or by email at brays@musc.edu.