Managing the unpredictable periods of illness caused by lupus is a constant struggle. Because lupus can mimic a variety of other diseases, it can be hard to find an appropriate option to deal with your symptoms. If you feel like you would like to take part in research to better understand lupus, you may be interested in participating in the LILAC clinical research study with an investigational medication.

To learn more about the study
and to see if you may qualify, visit
LupusLilacStudy.com

LILAC
LUPUS CLINICAL RESEARCH STUDY

LU-US-0021(1)
USA_ENG_10015643_230LE201B_BRPA-01_v3-0_2016-08-31

I have Lupus. Every day is different.

Battling Lupus is painful, exhausting, and can sometimes make you feel hopeless. You may have been able to do more yesterday because you didn't feel as sick as you do today.

LILAC
LUPUS CLINICAL RESEARCH STUDY

Why should I participate in a clinical research study?

Clinical research studies (also called clinical trials) test the safety and efficacy of investigational medications for diseases and conditions. Many treatments used today are the result of past clinical studies.

Participating in a study is a way to learn more about your disease and how to take care of your health. As a study participant, your lupus will be closely monitored under the guidance of the study doctor. You will receive all investigational study medication and study-related tests and procedures at no cost.

Study participation is voluntary, and you can leave the study at any time. Although you may not benefit directly from being in the study, the information gathered in the study may help others with lupus in the future. Talk with your doctor, family, and friends, and ask the study doctor questions about the study before you decide to participate.

The study doctors and their staff respect your privacy. Details about your health will not be shared with anyone who is not associated with this research study unless you have given your permission or except as required by law.

What is the LILAC study?

The LILAC study is a two-part clinical research study (Part A and Part B) for people with lupus erythematosus. You are being asked to consider participating in Part B.

Part B of the LILAC study will evaluate the efficacy of an investigational medication, called BIIB059, in reducing skin disease in people with cutaneous lupus erythematosus (CLE) with or without systemic lupus erythematosus (SLE) with skin activity (also referred to as lupus rash).

What is CLE and how is it treated?

CLE and SLE are autoimmune diseases, whereby your immune system attacks your body. CLE is limited to the skin and causes skin sores (lesions) and rashes. CLE is categorized into subgroups, such as DLE and SCLE, based on the characteristics of skin lesions present. People with CLE may sometimes also have SLE. SLE causes damage to multiple organ systems and presents a broad range of symptoms.

There are no medications currently approved to treat CLE. Topical corticosteroids, immunosuppressive drugs, and antimalarial medications are often used to reduce the severity of CLE symptoms. However, many of these therapies are only partially effective and may cause serious side effects when taken over a long period of time.

More research is needed to better understand how CLE works and to help develop medications that may target the underlying causes of CLE.

What is the investigational medication?

The investigational medication in the LILAC study, called BIIB059, is a monoclonal antibody. Antibodies recognize and attach to specific molecules in your body.

BIIB059 attaches to the surface of a specific type of cell that is part of the immune system. These cells produce a protein called interferon alpha (IFNα) that may be associated with CLE and SLE. When BIIB059 attaches to these specific immune system cells, it limits the production of IFNα. It is believed that having less of the IFNα protein in your body may help to control the symptoms and/or the disease activity of CLE and SLE including the skin manifestations of the disease.

BIIB059 will be administered as a subcutaneous injection (injection below the skin).

Who can participate?

You may be able to participate in Part B of the LILAC study if you:

- Are between 18 and 75 years of age
- Are diagnosed with CLE with or without SLE symptoms
- Have active CLE despite treatment with corticosteroids on your skin and/or an antimalarial for at least 3 months
- Have at least one active discoid lupus erythematosus (DLE) or one active subacute cutaneous lupus erythematosus (SCLE) lesion

The study staff will explain other criteria you will need to meet to qualify for Part B of the study.

What will happen if I join Part B of the study?

Participation in Part B of the study will last approximately 28 weeks and include up to 9 visits to the study site. If you decide to participate, you may be asked to slowly stop taking certain medications you are currently using to treat your CLE, but some of the medications you are currently taking for CLE might be continued.

If you participate in Part B of the study, you will be randomized to one of two groups. Randomized means you will be assigned by chance, similar to flipping a coin, to one of two treatment groups. For every two people assigned to receive BIIB059, one person will be assigned to receive placebo. A placebo is an inactive substance that looks just like the study drug. Neither you nor the study doctor/study staff will know which treatment group you have been assigned to, but the study doctor will be able to find out quickly if he/she needs to during the study. This kind of study design helps to remove any bias that may be introduced from knowing what treatment you received.

You will receive a total of 4 doses of BIIB059 or placebo over the course of 12 weeks. After your last dose of BIIB059 or placebo, you will visit the study site three to four more times.