Who Can Participate?

This study may be an option if you are at least 18 years old and meet the following requirements:

- Diagnosed with pulmonary sarcoidosis at least 6 months ago, and have experienced symptoms related to your pulmonary sarcoidosis in the past 6 months
- Vaccinated for COVID-19 (defined as the initial 2 vaccine course of Moderna or Pfizer vaccine, or a single J&J vaccine)
- If taking a corticosteroid (e.g. prednisone): On a stable dose of 25 mg/day or less for at least 4 weeks and are willing to reduce your dose under medical supervision throughout the study.
- If taking immunosuppressant therapy (e.g. methotrexate): On a stable dose for at least 3 months and are willing to stop immunosuppressant therapy if enrolled in the study.

For a complete list of criteria for participating in the RESOLVE-Lung Study, please contact the study team using the information provided on the back of this brochure.

Contact the Study Team to Learn More

CONTACT US:
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RESOLVE LUNG

IRB Approved at the
Protocol Level
Sep 09, 2022

Pulmonary Sarcoidosis Treatment Is Not One-Size-Fits-All.

If you are experiencing symptoms, consider a new research opportunity.

We're fighting to improve the lives of people with pulmonary sarcoidosis.

Sarcoidosis is a rare inflammatory disease characterized by the presence of tiny clumps of immune cells, called granulomas, that can occur in any organ or tissue. While there are some treatments available, they do not work for everyone and/or are poorly tolerated. There is a significant need for a more effective and better tolerated therapy for treating pulmonary sarcoidosis.

About This Study

The RESOLVE-Lung study is evaluating the safety and effectiveness of the investigational medicine namilumab for the treatment of pulmonary sarcoidosis. About 100 participants will be enrolled at study sites in the United States and Europe.

Participants will initially receive once monthly injections of namilumab or placebo (injection with no active ingredient) for approximately 6 months. After the initial treatment period, all participants will have the option to receive namilumab in a 6-month open-label extension, regardless of whether they were initially assigned namilumab or placebo.

What is Namilumab?

Namilumab is a human monoclonal antibody (mAb) believed to treat the underlying cause of sarcoidosis by inhibiting one of the key proteins responsible for the formation of sarcoidosis granulomas. Namilumab has been studied previously in over 300 people and was found to be well-tolerated with no serious side effects. It is considered investigational because it is not yet approved by the US Food and Drug Administration (or any other health authority) for any disease or condition.

Namilumab is given as a subcutaneous (under the skin) injection by a trained healthcare professional.

What are Possible Side Effects?

Namilumab has been well-tolerated in studies so far, with the most common side effects reported being influenza-like illness, runny nose, headache, temporary increases in liver function tests, and decreases in white blood cell count.

Because of the way namilumab works in the body, other possible side effects that could occur include infection, allergic reactions, and injection site soreness. A rare lung condition called pulmonary alveolar proteinosis is possible, but this has not been seen in any patients or volunteers to date.

There may be other side effects of namilumab that are not known at this time. Your study doctor will discuss with you the full list of potential risks of participating in the RESOLVE-Lung study.

Why Participate?

Clinical trials offer opportunities for patients to partner with researchers to help develop new treatments for serious diseases.

Possible benefits from taking part in the RESOLVE-Lung study may include:

- Access to the study medicine namilumab
- Relief of, or lessening of, the signs and symptoms of your pulmonary sarcoidosis
- Increased monitoring of your pulmonary sarcoidosis with a specialist provider
- Contributing to research which may help others with pulmonary sarcoidosis in the future
- There is no guarantee that you will experience any benefit

If you are a member of a racial or ethnic group historically underrepresented in clinical trials, participating in a clinical trial will help ensure the results better reflect the effectiveness and safety of a new therapy for everyone with pulmonary sarcoidosis.