What is **MINT**?

Myositis Interstitial
Lung Disease
Nintedanib Trial

Have you been diagnosed with pulmonary fibrosis (Interstitial Lung Disease, (ILD)) and have myositis (polymyositis, dermatomyositis, or antisynthetase syndrome) or have a positive myositis autoantibodies?

If so, you may be able to participate in a research study to understand the role of anti-fibrotic drugs in myositis associated ILD as well as advanced ILD and myositis research

The MINT trial is a research study using the drug, Nintedanib (Ofev®), an anti-fibrotic drug approved by the Food and Drug Administration (FDA) for the treatment of various types of ILD

Contact Us

If you or someone you know would like further information regarding this research study, please contact us!

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MINT

Myositis Interstitial Lung Disease Nintedanib Trial

A Remote Clinical Trial for Patients with Interstitial Lung Disease (Pulmonary Fibrosis) Associated with Myositis From Your Home <u>Anywhere</u> in USA

This novel clinical trial requires no visit to the study center

Study Website: Mint.Pitt.Edu





Study Purpose

- Myositis is a rare autoimmune disease that causes muscle inflammation often leading to muscle weakness.
- Many patients with myositis develop Interstitial Lung Disease (MA-ILD) or pulmonary fibrosis (lung scarring).
- Very limited treatments are available for MA-ILD
- Nintedanib is an anti-fibrotic drug that has already been approved for use in various types of ILD or pulmonary fibrosis.
- The purpose of this study is to help researchers understand if Nintedanib can be used as an effective and safe treatment for MA-ILD in combination with usual medication.

Could this study be right for you?

You must:

- Be 18 years of age or older
 - Live in United States (USA)
- Have been diagnosed with Interstitial Lung Disease (ILD) or Pulmonary fibrosis (scarring of lungs)
- Have been diagnosed with myositis (polymyositis, dermatomyositis, antisynthetase syndrome, etc)
 OR

have one of the myositis associated autoantibodies

Contact us to be considered

What to expect:

- First, you will be evaluated to determine your eligibility for the study
- Eligible participants will be asked to take Nintedanib or a placebo over the course of 12 weeks, followed by Nintedanib for another 12 weeks, along with their usual medications for ILD (pulmonary fibrosis)

Participants will:

- Take Nintedanib (study drug) or placebo as per the trial
- Have audio-video conferences with study doctor or staff
- Perform home testing, vitals, and complete questionnaires at home, with aid from study staff
- Travel to a location close to home for lung function testing and chest images
- A home nurse will perform blood collections in your home
- All study visits will be done remotely from the convenience of your home using a tablet and equipment provided by the study