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The STRATUS Study for patients with systemic sclerosis (SSc) that affects their lungs

Dear Scleroderma Foundation Support Group,

Our center is taking part in a clinical research study that is evaluating an investigational medication for people with systemic sclerosis (SSc) that affects their lungs. Systemic sclerosis can cause fibrosis (inflammation and scarring) of the lungs, which is known as SSc-associated interstitial lung disease (SSc-ILD). We are writing to you because we think that the STRATUS Study may be of interest to you. If, after reading this letter, you have any questions or want more information, please contact us using the information above.

We would like to tell you a little more about the study

We are looking for people to take part in the STRATUS Study who have SSc-ILD and are currently taking mycophenolate. The study will see if the investigational medication can safely and effectively treat SSc-ILD when it is given along with mycophenolate. The main purpose of this study is to find out if the investigational medication can improve the function of the lungs in patients with SSc-ILD. The study will also look at how the investigational medication affects the skin in people with SSc-ILD, and how SSc symptoms affect their quality of life.

Taking part in the STRATUS Study

The STRATUS Study will last for up to 120 weeks (about 2 years and 4 months) and will involve 31 visits to the study center. At each study visit, the study team will check your health, as well as your SSc symptoms.

If the study is suitable for you, you will be placed into one of three groups at random (like flipping a coin):

- One group will receive the investigational medication (at a dose of 1500 mg)
- One group will receive the investigational medication (at a dose of 500 mg)

- One group will receive placebo (which looks like the investigational medication but contains no actual medication).

No matter which group you are in, you must continue to take mycophenolate.

All study medication (investigational medication or placebo) will be given once every 4 weeks as an infusion (a drip into a vein in your arm). The infusion will take about 1 hour.

Who can take part?

You may be able to take part in the STRATUS Study if you:

- are 18–75 years of age, inclusive
- have been diagnosed with SSc that affects the lungs
- have been taking mycophenolate for at least 6 months to treat your SSc.

The study team will perform some tests and health assessments to see if the study is right for you. If you take part in the study, you will be monitored carefully by a team of doctors and nurses. All study-related medications and assessments will be provided at no cost to you. You do not have to take part in the STRATUS Study and can change your mind about taking part at any time.

It is hoped that the results of the study will help us determine if the investigational medication is safe and effective for the treatment of SSc-ILD. The data obtained from this study could help us to better understand SSc-ILD and gather information about a potential medication for this condition.

If you are interested in taking part in this study, or if you have any questions, please contact us.

Sincerely

Elizabeth Volkmann

Principal Investigator

The STRATUS Study