



Scleroderma Lung Study II:

Mycophenolate vs. Oral Cyclophosphamide
in Scleroderma Interstitial Lung Disease

☀ Home

☀ What is Scleroderma?

☀ What is the SLS II Study?

☀ The 12 Study Centers

☀ Results from SLS I Study

☀ For Physicians & Researchers

☀ Our Publications

☀ What is a Clinical Trial?

☀ Contact Us

The

CLINICAL & DATA COORDINATING CENTERS

at the David Geffen School of Medicine at UCLA



Welcome You

to the Scleroderma Lung Study II * Website

Click on a menu item from the left column to learn about Scleroderma-related Interstitial Lung Disease and the Scleroderma Lung Study II.

* Funded by a grant from the National Heart, Lung and Blood Institute (NHLBI) and the National Institutes of Health (NIH) with additional support provided by the David Geffen School of Medicine at UCLA.



Scleroderma Lung Study II:

Mycophenolate vs. Oral Cyclophosphamide in Scleroderma Interstitial Lung Disease

☀ Home

☀ **What is Scleroderma?**

☀ What is the SLS II Study?

☀ The 12 Study Centers

☀ Results from SLS I Study

☀ For Physicians & Researchers

☀ Our Publications

☀ What is a Clinical Trial?

☀ Contact Us

Scleroderma, also known as **systemic sclerosis (SSc)**, is an autoimmune disease in which the body attacks its own tissues, causing inflammation and an overproduction of collagen. Collagen is a fiber-like protein that connects tissues together and an overproduction produces thickening and scarring (also called fibrosis) in involved tissues. Individuals with SSc usually have prominent thickening and stiffening of the skin (scleroderma) and may suffer from fatigue, weight loss, and joint swelling and/or pain. More severe forms of the disease involve internal organs such as the gastrointestinal tract, heart, lungs, and kidneys. Current estimates are that between 75,000 to 100,000 Americans have the disease. While SSc can present at any age, the onset of disease occurs most commonly in individuals 30–50 years old. SSc occurs more frequently in woman than men, and in African Americans than Caucasians.

Patients may be diagnosed with either limited cutaneous SSc (lcSSc) or diffuse cutaneous SSc (dcSSc), the determination being based on the extent of their skin disease. While the progression of disease is highly variable, patients with dcSSc typically progress more rapidly and have a worse prognosis. In dcSSc, involvement of internal organs, such as pulmonary fibrosis, often develops within the first three years whereas in lcSSc, Raynaud's phenomenon and skin involvement may precede other manifestations by years or even decades. As of now, no treatments have proven effective and SSc is associated with a significant risk of premature death. In one population-based study of SSc patients, the average survival after diagnosis was 11 years, with those diagnosed with lcSSc living longer than those with dcSSc. Lung involvement, including the development of pulmonary hypertension and/or fibrosis of the lungs, is currently the leading cause of medical complications and premature death and is the focus of the Scleroderma Lung Study.



Scleroderma Lung Study II:

Mycophenolate vs. Oral Cyclophosphamide in Scleroderma Interstitial Lung Disease

☀ Home

☀ What is Scleroderma?

☀ What is the SLS II Study?

☀ The 12 Study Centers

☀ Results from SLS I Study

☀ For Physicians & Researchers

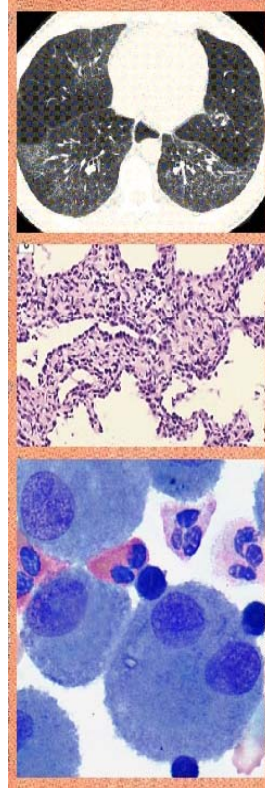
☀ Our Publications

☀ What is a Clinical Trial?

☀ Contact Us

Scleroderma Lung Disease:

Scleroderma is associated with two kinds of lung disease – interstitial lung disease (also called pulmonary fibrosis) and pulmonary hypertension. The Scleroderma Lung Study is focused on the treatment of pulmonary fibrosis. Pulmonary fibrosis occurs when scleroderma produces inflammation and scarring of the air sacs that make up lung tissue. When scar tissue forms in the lung, the tissue becomes thicker and stiffer, making it difficult for patients to take a normal breath and for the lungs to take up oxygen. Pulmonary fibrosis occurs in about 70-80% of people with both limited and diffuse scleroderma. Patients may not have symptoms with early disease but develop symptoms like increasing shortness of breath with exercise, cough, and dizziness as lung involvement progresses. Tests such as chest x-ray, CT scan the chest, and lung function studies are used to look at the degree of lung involvement. About 15% of patients with lung fibrosis progress to “severe” levels of lung disease. This decline typically happens during the first 4-6 years after onset of scleroderma.



Scleroderma Lung Study II (“SLS II”):

SLS II is a clinical research study focused on treating scleroderma-related pulmonary fibrosis. It is funded by a grant from the National Heart, Lung and Blood Institute of the National Institutes of Health. This study compares 2 different medications—daily oral cyclophosphamide (CYC, also called Cytoxan™) with daily oral mycophenolate mofetil (MMF, also called Cellcept™). Both medications have shown promise in stabilizing lung function in patients with pulmonary fibrosis. CYC was tested in a prior research study (SLS I) for scleroderma-related lung fibrosis and was associated with significant improvements that lasted for up to one year after the drug was stopped (see: “[Results from SLS I Study](#)”). In SLS II, MMF is being examined to see if it is as effective as CYC and to determine whether its effects might last longer. However, at this time, we don’t have enough information to know whether one medication works better or is safer than the other.



Scleroderma Lung Study II:

Mycophenolate vs. Oral Cyclophosphamide in Scleroderma Interstitial Lung Disease

☀ Home

☀ What is
Scleroderma?

☀ **What is the
SLS II Study?**

☀ The 12 Study
Centers

☀ Results from
SLS I Study

☀ For Physicians
& Researchers

☀ Our
Publications

☀ What is a
Clinical Trial?

☀ Contact Us

Participating in SLS II:

If you give your consent to participate in the SLS II research study and are found to be eligible to be enrolled as a study patient, you will be randomized to receive either daily cyclophosphamide (CYC, also called Cytoxan™) or mycophenolate mofetil (MMF, also called Cellcept™) as an experimental treatment for your lung disease. You can learn more about randomization and what it means to be involved in a research study in the section on "[What is a clinical trial](#)". Both of these study drugs are prepared as identical appearing capsules that are taken by mouth. This is a randomized double-blinded study, which means that neither the enrolled patients or their treating physicians will know which of the study drugs they are receiving. The study capsules will be taken twice daily for two years, although those patients enrolled into the group receiving CYC will only receive active drug for the first year and then an identical appearing placebo (sugar pill that contains no active medication) for the second year. Those patients that are assigned to the MMF group will receive active study drug for the entire two years.

The SLS II study is being conducted at 12 different centers throughout United States (see section on "[The 12 Study Centers](#)") and we plan to recruit a total of 150 patients to participate. Before you can participate in the study, you will have to provide past medical records about your disease and then undergo a series of tests to find out if you are eligible to be in the study. These tests include a complete history and physical examination, blood tests, lung function tests (also called pulmonary function tests), and a CT scan of your chest.

To be eligible to participate in SLS II, patients must meet the following criteria:

- Be between 18 and 75 years old
- Have either limited or diffuse scleroderma for no more than 5 years
- Have shortness of breath
- Have decreased lung function
- Not have other serious illnesses
- Meet other eligibility criteria that your study doctor will explain to you as part of the evaluation process.

If you are eligible, you will be randomized to receive treatment with either CYC or MMF as described above.

[Next page →](#)



Scleroderma Lung Study II:

Mycophenolate vs. Oral Cyclophosphamide in Scleroderma Interstitial Lung Disease

☀ Home

☀ What is Scleroderma?

☀ What is the SLS II Study?

☀ The 12 Study Centers

☀ Results from SLS I Study

☀ For Physicians & Researchers

☀ Our Publications

☀ What is a Clinical Trial?

☀ Contact Us

The premise for this study is that 2 years of daily MMF will be more effective and safer than one year of daily CYC. However, there is currently not enough evidence to know if this premise is true, which is why it is being tested in this research study.

Study-related visits:

Once you start the study drug, you will be checked at least monthly for study medication side effects. This will be monitored using urine and blood tests. You may or may not have to come to the study site for these tests. You will see the study doctor every 3 months to check the effectiveness and safety of the study drug. During these visits, you will have a physical examination, complete several questionnaires to see how well you are doing, and have a lung function study. At the end of the study you will also have another CT scan of the chest.

What happens if I don't do well or have side effects:

Being a voluntary study, you can drop out at anytime during the study. In addition, we have developed guidelines to ensure your safety. In case of certain types of adverse events or worsening of your scleroderma (including your lung disease), we may decide to decrease the dose of the study drug or completely take you off the study drug and work with your own doctor to start another therapy. In all cases you will be closely followed and your safety and treatment will be our first consideration.

Cost to you or your Health Insurance:

The costs of the study drugs and laboratory testing (blood and urine) for monitoring potential study drug toxicity, and the costs of attending the study center for each of the study visits, will be paid for by the study. However, the lung function tests and chest CT scans are considered standard of care for your condition and will be billed to your health insurance. If you have a co-payment, no insurance or your insurance does not cover the entire costs of these tests, then the study will cover these amounts for you. Other medical expenses that you may incur as part of the regular management of your scleroderma, which are not related to this specific study, will not be paid for by the study. You should discuss this with your study physician before you decide to participate in SLS II.



Scleroderma Lung Study II:

Mycophenolate vs. Oral Cyclophosphamide in Scleroderma Interstitial Lung Disease

☀ Home

☀ What is Scleroderma?

☀ What is the SLS II Study?

☀ The 12 Study Centers

☀ Results from SLS I Study

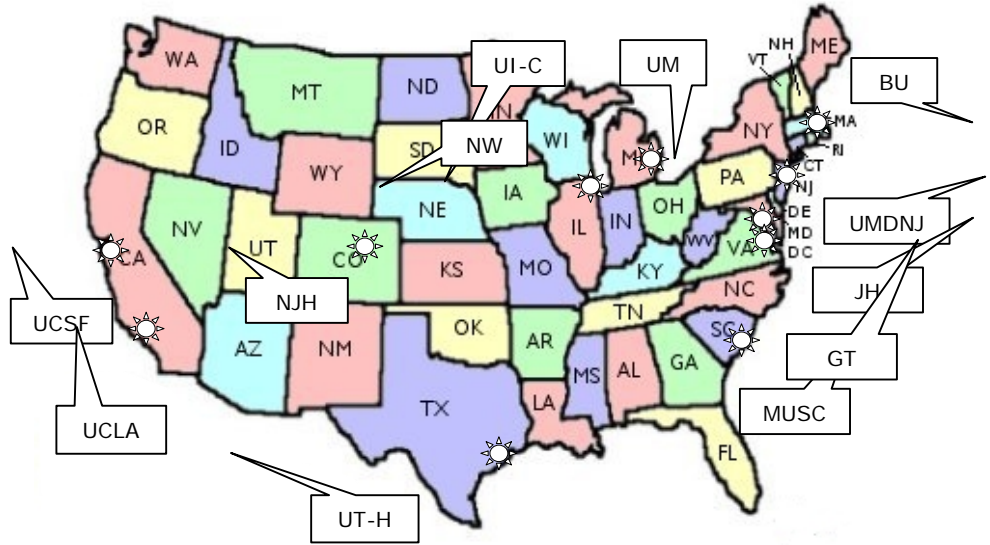
☀ For Physicians & Researchers

☀ Our Publications

☀ What is a Clinical Trial?

☀ Contact Us

We have 12 Clinical Centers conveniently located across the mainland United States



UCLA	David Geffen School of Medicine at UCLA*	Los Angeles, CA
BU	Boston University, School of Medicine	Boston, MA
NW	Feinberg School of Medicine, Northwestern University	Chicago, IL
GT	Georgetown University School of Medicine	Washington, DC
JH	Johns Hopkins University School of Medicine	Baltimore, MD
MUSC	Medical University of South Carolina	Charleston, SC
UCSF	University of California, San Francisco, School of Medicine	San Francisco, CA
NJH	University of Colorado, National Jewish Health	Denver, CO
UI-C	University of Illinois at Chicago, College of Medicine	Chicago, IL
UMDNJ	University of Medicine and Dentistry of New Jersey, Robert Wood Johnson Medical School	New Brunswick, NJ
UM	University of Michigan Medical School	Ann Arbor, MI
UT-H	University of Texas Medical School at Houston	Houston, TX

**Lead Clinical and Data Coordinating Centers*

Study Centers

Click for complete list of Study Centers and contact information in PDF format



Scleroderma Lung Study II:

Mycophenolate vs. Oral Cyclophosphamide in Scleroderma Interstitial Lung Disease

☀ Home

☀ What is Scleroderma?

☀ What is the SLS II Study?

☀ The 12 Study Centers

☀ Results from SLS I Study

☀ For Physicians & Researchers

☀ Our Publications

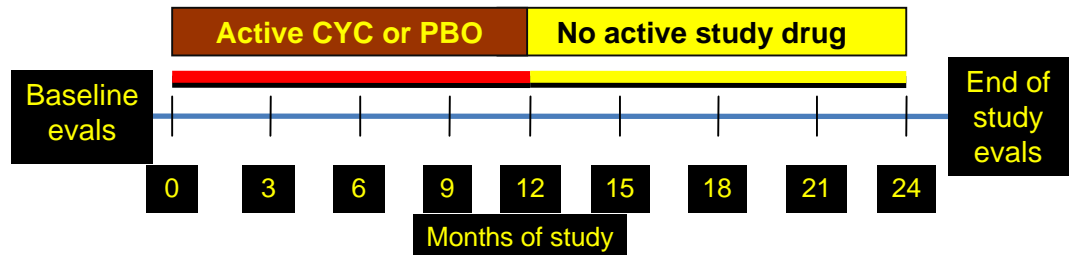
☀ What is a Clinical Trial?

☀ Contact Us

Results from SLS-I study

Scleroderma Lung Study I (SLS I) was a clinical research study that compared the efficacy and toxicity of daily oral cyclophosphamide (CYC, also called Cytoxan™) with a daily placebo pill for the treatment of scleroderma-related lung fibrosis. The duration of the study was for 1 year and the patients were followed for an additional year without treatment as outlined in the figure below.

SLS I study design



Patient's disease status was checked every 3 months during the two years.

The main findings from the SLS I study are summarized below (please see the section on "[Our Publications](#)" for complete scientific details):

A. At the end of 1 year treatment with CYC was:

1. Better than a placebo pill in stabilizing the lung function.
2. Better than a placebo pill in improving symptoms of shortness of breath.
3. Better than a placebo pill in improving quality of life and physical function.
4. Better than a placebo pill in improving skin thickness in patients with diffuse scleroderma.
5. Safe when side effects were closely monitored



Scleroderma Lung Study II:

Mycophenolate vs. Oral Cyclophosphamide in Scleroderma Interstitial Lung Disease

☀ Home

☀ What is Scleroderma?

☀ What is the SLS II Study?

☀ The 12 Study Centers

☀ **Results from SLS I Study**

☀ For Physicians & Researchers

☀ Our Publications

☀ What is a Clinical Trial?

☀ Contact Us

B. During additional follow up year (year #2)

1. The effect of CYC on lung function lasted for an additional 6 months but was no different than a placebo pill at the end of 2 years.
2. The effect of CYC on symptoms of shortness of breath continued at the end of 2 years.
3. The effect of CYC on physical function lasted for an additional 6 months after stopping the drug but was no different than a placebo pill at the end of 2 years.
4. The effect of CYC on skin thickness persisted at the end of 2 years.
5. There were no safety concerns with CYC at the end of 2 years.

In summary, the SLS I study showed that 1 year of oral CYC was effective in improving lung function, symptoms of shortness of breath, and quality of life but the effect on lung function and quality of life only lasted for another 6 months after CYC was stopped. CYC caused few serious side effects for most study patients when the drug was carefully monitored according to the protocol. SLS II builds on these findings and will compare CYC with MMF to learn which one provides the best outcomes after two years.



Scleroderma Lung Study II:

Mycophenolate vs. Oral Cyclophosphamide in Scleroderma Interstitial Lung Disease

The information contained on the following pages is technical in nature and is intended for physicians and researchers experienced in the care and investigation of Scleroderma and Scleroderma-related Interstitial Lung Disease. If you fit this description, please click the link below and then select the area of interest for further information about Scleroderma Lung Study II.

[Physicians and Health Care Providers
Click here](#)

☀ Home

☀ What is Scleroderma?

☀ What is the SLS II Study?

☀ The 12 Study Centers

☀ Results from SLS I Study

☀ **For Physicians & Researchers**

☀ Our Publications

☀ What is a Clinical Trial?

☀ Contact Us





Scleroderma Lung Study II:

Mycophenolate vs. Oral Cyclophosphamide in Scleroderma Interstitial Lung Disease

☀ Home

☀ What is Scleroderma?

☀ What is the SLS II Study?

☀ The 12 Study Centers

☀ Results from SLS I Study

☀ **For Physicians & Researchers**

☀ Our Publications

☀ What is a Clinical Trial?

☀ Contact Us

Additional Study Information for Physicians and Health Care Providers

[Inclusion/Exclusion Criteria](#)

[SLS II Protocol \(Brief Summary\)](#)

[Cyclophosphamide FDA Package Insert](#)

[Mycophenolate Mofetil FDA Package Insert](#)

[CellCept Medication Guide For Physicians](#)

[CellCept Medication Guide For Patients](#)

[Study Listing on ClinicalTrials.gov](#)

[SLS II Biological Specimen Repository Request Form](#)



Scleroderma Lung Study II:

Mycophenolate vs. Oral Cyclophosphamide in Scleroderma Interstitial Lung Disease

☀ Home

☀ What is Scleroderma?

☀ What is the SLS II Study?

☀ The 12 Study Centers

☀ Results from SLS I Study

☀ For Physicians & Researchers

☀ **Our Publications**

☀ What is a Clinical Trial?

☀ Contact Us

The Scleroderma Lung Study (SLS) Investigators have published our findings in a number of leading medical journals and this work may be of interest to patients, researchers and physicians. All of our publications are cited below.

Clicking on a reference will connect you with PubMed, an online library service provided by the U.S. National Library of Medicine. PubMed will provide access to the abstract summary of the paper and, depending upon your access rights, the entire publication may be available in either HTML or PDF format.

Publications in chronological order:

[Click here for:
PDF Version](#)

1. Khanna D, Clements PJ, Furst DE, Chon Y, Elashoff R, Roth MD, Sterz MG, Chung J, FitzGerald JD, Seibold JR, Varga J, Theodore A, Wigley FM, Silver RM, Steen VD, Mayes MD, Connolly MK, Fessler BJ, Rothfield NF, Mubarak K, Molitor J, Tashkin DP; Scleroderma Lung Study Group.

Correlation of the degree of dyspnea with health-related quality of life, functional abilities, and diffusing capacity for carbon monoxide in patients with systemic sclerosis and active alveolitis: results from the Scleroderma Lung Study.

Arthritis Rheum. 2005 Feb; 52(2):592-600.

2. Tashkin DP, Elashoff R, Clements PJ, Goldin J, Roth MD, Furst DE, Arriola E, Silver R, Strange C, Bolster M, Seibold JR, Riley DJ, Hsu VM, Varga J, Schraufnagel DE, Theodore A, Simms R, Wise R, Wigley F, White B, Steen V, Read C, Mayes M, Parsley E, Mubarak K, Connolly MK, Golden J, Olman M, Fessler B, Rothfield N, Metersky M; Scleroderma Lung Study Research Group.

Cyclophosphamide versus placebo in scleroderma lung disease.

N Engl J Med. 2006 Jun 22; 354(25):2655-66.

3. Cole JC, Khanna D, Clements PJ, Seibold JR, Tashkin DP, Paulus HE, Irwin MR, Motivala SJ, Furst DE on behalf of the Scleroderma Lung Study (SLS) and Relaxin Study.

Single-factor scoring validation for the Health Assessment Questionnaire-Disability Index (HAQ-DI) in patients with systemic sclerosis and comparison with early rheumatoid arthritis patients.

Qual Life Res. 2006 Oct 31, 15(8):1355-1371.



Scleroderma Lung Study II:

Mycophenolate vs. Oral Cyclophosphamide in Scleroderma Interstitial Lung Disease

☀ Home

☀ What is
Scleroderma?

☀ What is the
SLS II Study?

☀ The 12 Study
Centers

☀ Results from
SLS I Study

☀ For Physicians
& Researchers

☀ **Our
Publications**

☀ What is a
Clinical Trial?

☀ Contact Us

Publications Cont:

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Impact of oral cyclophosphamide on health-related quality of life in patients with active scleroderma lung disease: results from the scleroderma lung study.
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5. Elashoff RM, Li G, Li N.
An approach to joint analysis of longitudinal measurements and competing risks failure time data.
Stat Med 2007 Jun 30; 26(14):2813-35.
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Scleroderma Lung Study II:

Mycophenolate vs. Oral Cyclophosphamide in Scleroderma Interstitial Lung Disease

☀ Home

☀ What is Scleroderma?

☀ What is the SLS II Study?

☀ The 12 Study Centers

☀ Results from SLS I Study

☀ For Physicians & Researchers

☀ **Our Publications**

☀ What is a Clinical Trial?

☀ Contact Us

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Bronchoalveolar lavage and response to cyclophosphamide in scleroderma interstitial lung disease.
Am J Respir Crit Care Med. 2008 Jan 1;177(1):91-8.
9. Kim HJ, Li G, Gjertson D, Elashoff R, Shah SK, Ochs R, Vasunilashorn F, Abtin F, Brown MS, Goldin JG.
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Oral Cyclophosphamide for Active Scleroderma Lung Disease: A Decision Analysis.
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Robust joint modeling of longitudinal measurements and competing risks failure time data.
Biom J. 2009 Feb;51(1):19-30.
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Surfactant protein D and KL-6 as serum biomarkers of interstitial lung disease in patients with scleroderma.
J Rheumatol. 2009 Apr;36(4):773-80. Epub 2009 Mar 13.



Scleroderma Lung Study II:

Mycophenolate vs. Oral Cyclophosphamide in Scleroderma Interstitial Lung Disease

☀ Home

☀ What is
Scleroderma?

☀ What is the
SLS II Study?

☀ The 12 Study
Centers

☀ Results from
SLS I Study

☀ For Physicians
& Researchers

☀ Our
Publications

☀ **What is a
Clinical Trial?**

☀ Contact Us

What is a Clinical Trial?

Choosing to participate in a clinical trial is an important personal decision. Answers to the following frequently asked questions about clinical trials are provided by ClinicalTrials.gov, a service of the U.S. National Institutes of Health. They provide detailed information about clinical trials.

Click on a question below to read their answer or access this section of the ClinicalTrials.gov website directly online at:

<http://www.clinicaltrials.gov/ct2/info/understand>

Frequently asked questions:

- [What is a clinical trial?](#)
- [Why participate in a clinical trial?](#)
- [Who can participate in a clinical trial?](#)
- [What happens during a clinical trial?](#)
- [What is informed consent?](#)
- [What are the benefits and risks of participating in a clinical trial?](#)
- [What are side effects and adverse reactions?](#)
- [How is the safety of the participant protected?](#)
- [What should people consider before participating in a trial?](#)
- [What kind of preparation should a potential participant make for the meeting with the research coordinator or doctor?](#)
- [Does a participant continue to work with a primary health care provider while in a trial?](#)
- [Can a participant leave a clinical trial after it has begun?](#)
- [Where do the ideas for trials come from?](#)
- [Who sponsors clinical trials?](#)
- [What is a protocol?](#)
- [What is a placebo?](#)
- [What is a control or control group?](#)
- [What are the different types of clinical trials?](#)
- [What are the phases of clinical trials?](#)



Scleroderma Lung Study II:

Mycophenolate vs. Oral Cyclophosphamide in Scleroderma Interstitial Lung Disease

☀ Home

☀ What is Scleroderma?

☀ What is the SLS II Study?

☀ The 12 Study Centers

☀ Results from SLS I Study

☀ For Physicians & Researchers

☀ Our Publications

☀ What is a Clinical Trial?

☀ Contact Us

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Study Centers

*Click for complete list of Study Centers
and contact information in PDF format*