

## **VIDEO TRANSCRIPT**

### **Scleroderma: Cyclophosphamide Or Transplantation**

## **SCREENING PHASE**

**Length 10:48 minutes**

<p>SCOT logo</p> <p>Text on screen: Screening Phase Length: 10:48</p>	<p>Music</p>
<p>Text on screen: SCOT is sponsored by the National Institutes of Health (NIH) through its Division of Allergy, Immunology and Transplantation (DAIT) in the National Institute of Allergy and Infectious Diseases (NIAID).</p>	<p>Music</p>
<p>Dr. Leslie Crofford, University of Kentucky, sitting in a chair.</p>	<p>Dr. Leslie Crofford: Hello. I am Dr. Leslie Crofford, a rheumatologist at the University of Kentucky and an investigator in the SCOT study. SCOT stands for Scleroderma Cyclophosphamide Or Transplantation. This is a clinical research study designed by experts in rheumatology and stem cell transplantation. It is sponsored by the National Institutes of Health.</p> <p>The purpose of this video is to help you learn— What SCOT is about. Why the SCOT study is important, and if you should consider participating. Let's begin with some facts about scleroderma.</p>
<p>Text on screen: Scleroderma Facts</p> <p>Image of back of female with hand on shoulder.</p> <p>Image of pathology slide. Blue stain area labeled "collagen."</p> <p>Image of female's arm and hand.</p>	<p>Dr. Leslie Crofford: The word scleroderma means "hard skin." No one knows the specific cause of scleroderma, but medical scientists are working hard to solve this mystery.</p> <p>For unknown reasons, the immune system of the body malfunctions, attacking itself and causing inflammation and overproduction of collagen. Collagen is a major component of connective tissue, which is what holds all of the structures in the body together.</p> <p>This disease is probably due to a number of genetic factors and is triggered by some outside stimulus. But since no one knows what the specific genetic and external factors are, there's no way to prevent the disease.</p>
<p>Text on screen: Who is Affected</p> <p>Image of pedestrians crossing the street.</p>	<p>Dr. Leslie Crofford:  An estimated 75,000 to 100,000 Americans have scleroderma.</p>

Image of female.  Partial image of the American flag with text "USA"	Women are about 4 times more likely to develop scleroderma than men. It occurs most frequently between the ages of 30 and 50, and is more common in the United States than in Europe.
Text on screen: Symptoms of the Disease	Dr. Leslie Crofford: General symptoms of this disease can appear gradually or suddenly and may include—
Image of Raynaud's attack of the hand. Palm and all fingers are pink. One finger is blanched white.	Dr. Leslie Crofford: Raynaud's phenomenon, which is a condition characterized by episodes of decreased blood flow to the fingers or toes after cold exposure or stress.
Image of swollen hands.  Image of hand with shiny skin and loss of a finger.	Dr. Leslie Crofford: <ul style="list-style-type: none"> <li>■ Unexplained swelling or thickening of the skin on the hands, feet, and face, and eventually other areas of the body,</li> <li>■ Loss of skin elasticity,</li> <li>■ Skin changes such as darkening or loss of pigment,</li> <li>■ Shiny appearance of the skin,</li> </ul>
Image of female with hand on neck.	Dr. Leslie Crofford: <ul style="list-style-type: none"> <li>■ Shortness of breath or trouble taking deep breaths,</li> <li>■ Trouble swallowing and acid reflux,</li> </ul>
Image of x-ray of knee joint. X-ray of a hand.	Dr. Leslie Crofford: <ul style="list-style-type: none"> <li>■ Painful, tender, or swollen joints,</li> <li>■ Trouble bending the fingers,</li> <li>■ Muscle weakness, and</li> <li>■ Fatigue.</li> </ul>
Dr. Leslie Crofford, University of Kentucky, sitting in a chair.	Dr. Leslie Crofford: With severe scleroderma, the organs and skin first become inflamed and then harden and stiffen from scarring and excess collagen deposits. Some organs may stop working altogether.
Text on screen: Prognosis Image of physician using a stethoscope to listen to a female patient's heart.	Dr. Leslie Crofford: At present, there is no cure for scleroderma. Disease involvement of the major organs is the single most important factor affecting survival. Half of the patients with the most severe organ involvement die within 5 years.
Image of medication bottle.	Dr. Leslie Crofford: Scleroderma renal crisis is a very serious kidney problem which used to be the leading cause of death in patients with scleroderma. Fortunately, through improvements in early detection and treatment, patient survival today has improved. Currently, lung damage and complications are responsible for the greatest number of deaths.
Text on screen: Treatment	Dr. Leslie Crofford: It is very difficult to treat scleroderma. No single treatment has

Image of a physician with patient.	been proven to prevent the disease from advancing or to reverse damage to the internal organs. Since scleroderma affects patients differently, doctors tailor therapy to manage organ-specific symptoms.
Image of 2 prescription medication bottles. Image of a hand with medication bottle.  Image of non-specific nuclear imaging scan.	Dr. Leslie Crofford: Examples of organ-specific treatments include medications such as— <ul style="list-style-type: none"> <li>■ ACE inhibitors, which are blood pressure medications that are effective for scleroderma kidney or renal crisis.</li> <li>■ Calcium-channel blockers, which are useful at managing Raynaud’s attacks, and</li> <li>■ Proton-pump inhibitors, which improve symptoms of acid reflux.</li> </ul> Unfortunately, these medications do not affect scleroderma-associated lung, muscle, or joint disease.
Silhouette of female body.	Dr. Leslie Crofford: Organ-specific treatment is important and helpful. However, since scleroderma is an autoimmune disease, some experts believe that a broader and possibly more effective approach might be to treat the patient’s immune system as a whole.
Text on screen: Study Arms	Dr. Leslie Crofford: In the SCOT study, investigators will examine the following immune-based approaches:
Text on screen: High-dose immunosuppressive therapy followed by stem cell transplantation vs. High-dose monthly Cytoxan (cyclophosphamide)	Dr. Leslie Crofford: High-dose immunosuppressive therapy followed by stem cell transplantation and high-dose monthly Cytoxan
Image of healthcare workers in an office talking.  Image of healthcare workers discussing and reading a medical chart.  Image of IV bags.	Dr. Leslie Crofford: Specifically, the SCOT investigators want to find out— <ul style="list-style-type: none"> <li>■ Is it more effective to treat patients who have severe scleroderma with stem cell transplant or high-dose monthly Cytoxan?</li> <li>■ Can either of these two study procedures slow down or stop scleroderma from becoming more severe?</li> <li>■ Can either of these study procedures reverse the physical effects of the disease?</li> <li>■ How safe are the study procedures for patients with severe scleroderma?</li> <li>■ Which of these study procedures has a more positive impact on a patient’s quality of life?</li> </ul>

Image of IV blood bag.	Dr. Leslie Crofford: It's important for you to understand that in the SCOT study only "autologous" stem cell transplants will be performed. This means that the blood stem cells will come from your own body—no embryonic or "donor" stem cells will be used.
Image of scientist looking through microscope.  Laboratory staff preparing blood samples.	Dr. Leslie Crofford: The initial idea for using stem cell transplantation comes from animal experiments and from observations doctors made while treating cancer patients who also happened to have autoimmune disease. What these researchers found was that patients seemed to have an improvement in their autoimmune disease after undergoing bone marrow transplantation. And in some cases, the autoimmune disease went into long-term remission after the transplant.
Images of IV bags.  X-ray of lungs.	Dr. Leslie Crofford: High-dose monthly Cytoxan is being tested because we believe it reduces the number of immune cells thought to be causing scleroderma. Although Cytoxan has been used to treat autoimmune diseases, such as lupus and scleroderma, the dose being used in the SCOT study is higher and the length of administration is longer than what is normally prescribed. This decision to test the higher dose is based on a variety of reports that have suggested that it may slow down the damage occurring in the lungs.
Text on screen: What's Involved	Dr. Leslie Crofford: The SCOT study is appropriate only for those with scleroderma who have extensive skin and early-onset internal organ involvement.
Patient having BP measured by healthcare provider. Healthcare provider reviewing a form.  IV bags.	Participation in this study is divided into 2 phases: screening and study procedure. The screening phase will evaluate individuals with scleroderma to see if they qualify for enrollment in the study. Once a participant completes the screening phase and is found to be eligible and agrees to take part, he or she will be assigned randomly to 1 of the 2 study groups— stem cell transplant or high-dose Cytoxan.
Image of physician writing in a medical chart.	Dr. Leslie Crofford: In clinical research studies such as SCOT, assignments are made randomly to ensure that there is an equal balance between the groups. It also means that you and your doctor will not be able to decide which study procedure you receive.
Text on screen: Screening Phase	Dr. Leslie Crofford: If you would like to be screened for this study, you will need to sign a screening consent form.

<p>Image of patient having blood pressure taken.</p> <p>Image of female on the phone.</p> <p>Image of laboratory worker holding and looking at lab specimen.</p> <p>Image of a laboratory worker reviewing a report.</p>	<p>Dr. Leslie Crofford: The screening process is designed to check your disease condition and determine if you are eligible for the study. This process can last 1 to 2 months and will take place at a participating SCOT study center. Depending on where you live, you may have to travel. You can talk with your SCOT study staff to find out more information on your specific travel needs and reimbursement options.</p> <p>During the screening phase, you will have a variety of tests performed and blood samples drawn to find out how scleroderma has affected your internal organs. These tests will be used to check the function of your heart, lungs, gastrointestinal system, and kidneys.</p>
<p>Images of SCOT brochures and consent form.</p> <p>Patient having an electrocardiogram.</p>	<p>Dr. Leslie Crofford: These tests are listed in your patient brochure and in your consent form. Based on the results of these tests, your doctor may decide that you're not eligible or not a good candidate for SCOT. If this occurs, he or she will explain the reasons why you should not participate.</p> <p>You are not required to enter the study-procedure phase. You may withdraw your consent and not continue in the study. Your doctor will discuss other available treatment strategies with you.</p>
<p>Text on screen: Additional Information</p> <p>Dr. Crofford sitting in a chair.</p>	<p>Dr. Leslie Crofford: All SCOT participants will need preapproval from their insurance carrier before enrolling. Please refer to your consent form for more information about any possible costs involved with taking part in this study.</p>
<p>Image of SCOT logo on screen.</p> <p>Dr. Crofford sitting in a chair.</p>	<p>Dr. Leslie Crofford: If you'd like to hear more about SCOT, please watch the separate patient video on the study-procedure phase. In that video, you will learn more about the 2 groups being studied and what participation would require. Thank you for your time.</p>
<p>Text on screen: Both of the SCOT study procedures are considered investigational and are not available as standard medical treatment.</p> <p>Please carefully review the SCOT study consent forms to decide if this research study is right for you.</p>	<p>Music</p>

Text on screen: Produced by Duke Clinical Research Institute, 2005	
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