

have you seen this patient?

- Rapidly progressing systemic sclerosis (SSc)
- Early internal organ involvement
- Diffuse skin involvement

Refer to the back of this card for a partial list of the inclusion/exclusion criteria.

study design:

Patients with diffuse, cutaneous systemic sclerosis (SSc) will be enrolled.



Subjects will be randomly assigned in a 1:1 ratio to receive either:

High-dose immunosuppressive therapy (HDIT) with autologous stem cell transplantation

OR

Monthly pulse IV cyclophosphamide for 12 months



Subjects will be followed for up to 62 months.

primary study objective:

To evaluate the potential benefit of HDIT and autologous stem cell transplant as treatment for severe SSc by comparing event-free survival in subjects receiving HDIT followed by stem cell transplantation versus subjects treated with high-dose cyclophosphamide therapy alone.

Please refer ALL potential patients to:
1.866.909.SCOT(7268) [toll free]
contact@sclerodermatrial.org



Scleroderma: Cyclophosphamide Or Transplantation

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).

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inclusion criteria:

- 18 to 69 years of age, inclusive
- Diffuse, cutaneous SSc as defined by the ACR criteria
- Duration of SSc \leq 5 years from the onset of first non-Raynaud's symptom
- 1 of the following:
 - SSc-related pulmonary disease

OR

- History of SSc-related renal crisis or disease

exclusion criteria:

- Pulmonary, cardiac, hepatic, or renal impairment that would limit therapy and compromise survival
- Previous treatment with cyclophosphamide (Cytoxan, CTX) as follows:
 - Prior IV CTX for $>$ 6 months or total cumulative dose $>$ 3 g/m²
 - Prior oral CTX for $>$ 4 months regardless of dose, or
 - Prior combination of oral and IV doses for $>$ 6 months regardless of dose
- Comorbid illnesses with an estimated median life expectancy $<$ 5 years

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