

# TBI Using IMRT and Cyclophosphamide Prior to Stem Cell Transplant for the Treatment of Severe Systemic Sclerosis

NCT04380831

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<b>Status</b>	RECRUITING
<b>Phase</b>	Early Phase 1
<b>Sponsor</b>	City of Hope Medical Center
<b>Enrollment</b>	15 participants

## Key Eligibility Criteria

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### Inclusion (6)

- Karnofsky performance status (KPS)  $\geq 70$
- Systemic sclerosis patients evaluated within 30 days of start of conditioning regimen who would be candidates for TBI-cyclophosphamide (Cy) per City of Hope (COH) guidelines and standard operating procedures (SOP) for autologous hematopoietic cell transplant
- Patients must be suitable for TBI conditioning regimens as part of transplant per radiation the referring hematologist
- Patients must have adequate organ function for HCT as determined by the hematologist
- Women of child-bearing potential and men must agree to use adequate contraception (hormonal or barrier method of birth control or abstinence) prior to study entry and for six months following duration of study participation
- ... and 1 more (see full listing online)

### Exclusion (4)

- Patients should not have any uncontrolled illness including ongoing or active infection
- Prior history of radiation therapy must be presented to study principal investigator (PI) for eligibility determination
- Pregnant women are excluded from this study because total body irradiation is an agent with the potential for teratogenic or abortifacient effects
- Subjects, who in the opinion of the investigator, may not be able to comply with the safety monitoring requirements of the study

## Locations (1 total)

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City of Hope Medical Center, Duarte, California, United States