



Halt-MS

High-dose immunosuppression and autologous bone marrow transplantation for poor prognosis multiple sclerosis

A multicenter clinical trial sponsored by the National Institutes of Health

HALT-MS is recruiting patients with relapsing–remitting MS fairly early in their disease course who have failed at least one DMT. Additional information is available on the study website at www.HALT-MS.org.

Treatment Summary

Autologous CD34 stem cell transplantation (HCT) following an intensive immunotherapy conditioning regimen:

- conditioning via BEAM chemotherapy (carmustine, etoposide, cytarabine, and melphalan) and antithymocyte globulin (ATG)
- mobilization of autologous peripheral blood hematopoietic progenitor cells achieved by G-CSF and prednisone

Active treatment period is ~3 months from initiation of mobilization to the day of discharge after transplant

Follow-up

Five (5) year post-treatment follow-up period, with 8 required study visits that will, at various times, involve: blood and urine collection, MRI studies, leukapheresis and neurology exams.

Study Design

Halt-MS is a prospective, multicenter, Phase II trial of thirty (30) subjects with poor prognosis MS.

Rationale

Previous exploratory studies (19 subjects) showed that BEAM/ATG conditioning prior to HCT can lead to clinical stabilization and improvement in patients with previously high disease activity[†].

[†]Saccardi, R. et al, Blood, 2005. 105: 2601-7

Inclusion Criteria:

- Relapsing remitting MS with cumulative disability, or progressive relapsing MS
- Duration of MS <15 years from diagnosis
- EDSS 3.0-5.5 (functional system changes in cerebral/mental functions and in bowel and bladder functions not taken into consideration in determining EDSS for protocol eligibility)
- T2 abnormalities on brain MRI consistent with MS
- 2 or more relapses in 18 months or less on IFN or GA, or cytotoxic therapy with EDSS increase > 0.5 maintained for > 4 weeks

- OR -

at least 3 gadolinium-enhancing lesions on MRI, obtained 3-4 months after relapse.

Exclusion Criteria:

- Primary progressive MS
- Secondary progressive MS without relapses for \geq 12 months

REFERRING INFORMATION

For questions regarding eligibility or to refer patients to the HALT-MS study, please contact one of the clinical sites listed below.

Houston, TX (MD Anderson) (713) 745-3055

Houston, TX (Baylor College of Med) (713) 798-6097

Seattle, WA (Fred Hutchinson) (206) 667-4916

Columbus, Ohio (OSU MS Center) (614) 293-7877



Sponsored by the National Institute of Allergy and Infectious Diseases
and conducted by the Immune Tolerance Network.