

Clinical trial protocol

Title

A Randomized Double Blinded Placebo-Controlled Phase III Trial Comparing Cyclosporine Plus Steroids With or Without Myfortic as Primary Treatment for Extensive Chronic Graft Versus Host Disease

Inclusion Criteria

Ages Eligible for Study: 18 Years - 60 Years, Genders Eligible for Study: Both

- Age 18 – 60
- Any primary diagnosis requiring treatment by hematopoietic stem cell transplantation
- Recipient of a single allogeneic stem cell transplant (bone marrow or peripheral blood stem cells, or cord blood) minimum 80 days ago
- Received a graft from a related or an unrelated donor
- Conditioning regimen: Myeloablative or non-myeloablative
- Patients suffering a first episode of extensive chronic GvHD, without recurrent disease
- The diagnosis of chronic GvHD requires the following:
 - Distinction from acute GvHD
 - Presence of at least one diagnostic clinical sign of chronic GvHD or presence of at least one distinctive sign confirmed by pertinent biopsy or other relevant diagnostic tests
 - Exclusion of other possible diagnoses
- Receiving a standard prophylaxis regimen for acute GvHD: CsA plus methotrexate, or CSA+MMF for NMA, or a T-cell depleted transplant
- Patient gives written informed consent prior to randomization

Exclusion Criteria

- Patient age less than 18 years or over 60 years.
- GvHD prophylaxis by tacrolimus plus methotrexate
- Delayed onset acute GvHD following NMA or DLI
- Second allogeneic stem cell transplant
- Not the first episode of chronic GvHD needing systemic immunosuppressive therapy.
- Limited chronic GvHD (Seattle criteria, see Appendix 1)
- Uncontrolled systemic infection which in the opinion of the investigator is associated with an increased risk of the patient's death within 1 week of randomization
- In the opinion of the investigator, if the patient has significant medical or psychosocial problems or unstable disease status

Start of the study

May 2006

Expected completion

March 2009

Expected Total Enrollment

200

Drug

Myfortic

National monocenter study