

Soluble Tumor Necrosis Factor Receptor: Enbrel® (Etanercept) for the Treatment of Acute, Non-infectious Pulmonary Dysfunction (Idiopathic Pneumonia Syndrome) Following Allogeneic Stem Cell Transplantation. ASCT0521

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Synopsis:

This is a phase II study of the experimental drug Enbrel® (etanercept) given in combination with corticosteroids to treat IPS. A phase II study is done to find out how well the drug improves a disease. A safe dose (the highest dose without too many side effects) has already been found in a phase I clinical trial that has been completed.

The primary objective is to determine the response rate to study therapy (etanercept + corticosteroids) in patients with IPS. Response will be defined as both (a) survival to day 28 and (b) the complete discontinuation of supplemental oxygen support by Day 28 of study.

The secondary objectives are:

- To estimate the Day 56 survival rate and the overall survival distribution following initiation of etanercept + corticosteroid therapy for patients with IPS.
- To determine the pulmonary response in patients with IPS treated with etanercept + corticosteroid therapy. Pulmonary response is defined as the time to discontinuation of supplemental oxygen therapy.
- To evaluate the toxicity of etanercept therapy in patients with IPS.
- To evaluate levels of pro-inflammatory cytokines, in both BAL fluid and serum, in patients with IPS.
- To describe C-reactive protein (CRP) levels at baseline, Day 7, 14, 21 and 28 and their association with response in patients with IPS.