



DELIVER Study

A study to evaluate delivery of Natalizumab (Tysabri®)

Study Rationale: While other Multiple Sclerosis medications can be administered at home, Natalizumab is given through IV at infusion centers. This can be costly and inconvenient to patients, especially if there is not an infusion center nearby.

Study Objective: The objective of the study is to determine if Natalizumab can be given by subcutaneous (SC) injection (under the skin). This will be accomplished through laboratory blood work, clinical assessments, and MRI scans.

Study Description: The study is sponsored by Biogen Idec. Neurologist Dr. Ronald Murray will oversee all study activities at IMMUNOe Health Centers.

New participants will be assigned to either Group D or Group E (in white):

Group A IV	Group B SC	Group C IM	Group D SC	Group E IV	Group F Reference
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Participation in Groups D or E will last approximately 8 months and will include 22 office visits and 8 MRIs.

Eligibility will be assessed at the first visit (Screening Visit).

If qualified, the patient will receive either an infusion or injection of Natalizumab (Baseline visit) Following the Baseline treatment, patients will return for 10 blood draws.

The blood draws will occur daily for the next four days post treatment (treatment is usually on Mon and blood draws are sch. for Tues, Wed, Thurs, Fri).

The next 6 blood draws will occur weekly for the following 2 months after treatment.

After 2 months, patients will resume a monthly schedule of treatment visits for the next 6 months.

Patient Profile (for Groups D and E):

- Male and Females between 18 to 65
- Diagnosed with Relapsing Forms MS (No SPMS or PPMS patients)
- Must be Tysabri Naïve
- EDSS between 0 and 6.5 (wheel chair bound = 7 and these patients are excluded)
- No other conflicting medical condition which would jeopardize the patient or study data
- Able to undergo an MRI (lasting an hour)

Costs: There is no cost to participate. You may be reimbursed for any reasonable travel costs as a result of your participation in this study.

Information: contact Lauren Friedman at 303-224-4671 or Lfriedman@immunoe.com