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RESEARCH/CLINICAL UPDATE

Keyword:	Tysabri (natalizumab)
Section:	TREATMENTS, APPROVED
CC:	Chapter Presidents

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MS TRIAL ALERT:
Five U.S. Sites Enrolling to Evaluate Effects of Tysabri on Vaccination

Summary: Researchers nationwide are enrolling people who have relapsing forms of MS in a study to evaluate the effects of Tysabri® (natalizumab, Biogen Idec and Elan Pharmaceuticals) on vaccination. Sites will recruit approximately 46 patients for this study, which is funded by Biogen Idec.

For the purposes of this study, "relapsing forms of MS" would include individuals who experience repeated, acute attacks or relapses of symptoms, followed by periods of full or partial recovery.

Rationale: Tysabri is a laboratory-produced monoclonal antibody that has been approved for marketing by the U.S. FDA for relapsing forms of MS. Tysabri is designed to hamper the movement of potentially damaging immune cells from the bloodstream, across the "blood-brain barrier," and into the brain and spinal cord. The drug inhibits this movement by attaching to alpha 4-integrin, a protein on the surface of immune T-cells that normally enables them to adhere to and pass through the blood-brain barrier.

Vaccines are an important part of healthy living with MS; most are safe for people with this disease. No information is available on how the immune system modulation of Tysabri affects the immune response that occurs when people receive vaccinations. This study is designed to determine whether Tysabri affects immune responses to vaccines.

Eligibility and Details: To enroll in this study, people must be between 18 and 50 years of age and have a diagnosis of a relapsing form of MS.

Participants will be randomly assigned to one of two groups: approximately 23 participants will receive Tysabri infusions (300 mg) intravenously every four weeks for at least nine months; along with three immunizations of keyhole limpet hemocyanin (KLH, a vaccine used to study the immune system) and one tetanus vaccine. Investigators are using these vaccinations to determine the response to a vaccine that participants would not have received before (KLH) and one that they would have received before (tetanus).

The second group of approximately 23 participants will receive no Tysabri treatment; but will have the same vaccinations as first group; three immunizations of KLH and one tetanus vaccine.

All participants will have blood drawn to determine effects on the immune response.

Contact: For enrollment information, please email neurologyclinicaltrials@biogenidec.com. Sites are enrolling in the following cities:

Fullerton, CA
Seattle, WA
Charlotte, NC
Charleston, WV
Oklahoma City, OK

-- Research & Clinical Programs Department

The National MS Society is proud to be a source of information about MS. Our comments are based on professional advice, published experience and expert opinion, but do not represent individual therapeutic recommendation or prescription. For specific information and advice, consult your personal physician.