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Efficacy and Safety of BG00012 in MS

This study has been completed.

Sponsor:
Biogen

Information provided by:
Biogen

ClinicalTrials.gov Identifier:
NCT00168701

First received: September 9, 2005
Last updated: November 14, 2007
Last verified: November 2007
History of Changes

Full Text View | Tabular View | No Study Results Posted | Disclaimer | How to Read a Study Record

Purpose

Determine the efficacy,safety, and tolerability of BG00012 in MS patients.

Condition	Intervention	Phase
Multiple Sclerosis	Drug: BG00012	Phase 2

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double-Blind
Primary Purpose: Treatment

Official Title: Double-Blind, Placebo-Controlled, Dose-Ranging Study to Determine the Efficacy and Safety of BG00012 in Subjects With Relapsing-Remitting Multiple Sclerosis

Resource links provided by NLM:

Genetics Home Reference related topics: multiple sclerosis

MedlinePlus related topics: Multiple Sclerosis

Drug Information available for: Dimethyl fumarate

U.S. FDA Resources

Further study details as provided by Biogen:

Primary Outcome Measures:

- The primary endpoint for the primary objective is the total number of MRI lesions at Weeks 12, 16, 20, and 24.

Secondary Outcome Measures:

- The secondary endpoints will include measuring the changes in MRIs from baseline until Week 24, changes in other MS measurements q12 weeks, and the annualized relapse rate and proportion of changes at Weeks 24 and 48.

Estimated Enrollment: 260
Study Start Date: October 2004
Study Completion Date: March 2006

Detailed Description:

Coalition Exhibit 1040
Coalition v. Biogen
IPR Unassigned

Eligibility

Ages Eligible for Study:	18 Years to 55 Years
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

1. Must be 18 to 55 years old, inclusive, at the time of informed consent.
2. Must have a confirmed diagnosis of relapsing-remitting MS according to McDonald criteria #1-4 (McDonald et al, 2001; Appendix 2).
3. Must have a baseline EDSS between 0.0 and 5.0, inclusive.

5. Must have experienced at least one relapse within the 12 months prior to randomization, with a prior cranial MRI demonstrating lesion(s) consistent with MS OR show evidence of Gd-enhancing lesions of the brain on an MRI performed within the 6 weeks.

6. Male and female subjects must be willing to take appropriate measures to prevent pregnancy.

Exclusion Criteria:

1. Primary progressive, secondary progressive, or progressive relapsing MS (as defined by Lublin and Reingold, 1996 [Appendix 3]).
2. History of malignancy.
3. History of severe allergic or anaphylactic reactions or known drug hypersensitivity.
4. History of abnormal laboratory results indicative of any significant cardiac, endocrinologic, hematologic, hepatic, immunologic, metabolic, urologic, pulmonary, gastrointestinal, dermatologic, psychiatric, renal, neurologic (other than MS), and/or other major disease.
5. History of human immunodeficiency virus (HIV).
6. History of drug or alcohol abuse (as defined by the Investigator) within the 2 years prior to randomization.
7. An MS relapse that has occurred within the 50 days prior to randomization AND/OR the subject has not stabilized from a previous relapse prior to randomization.
8. Body weight >100 kg.
9. Positive for hepatitis C antibody and/or positive for hepatitis B surface antigen (HBsAg) at screening.
10. Any of the following abnormal blood tests at screening.
11. Any previous treatment with FUMADERM®, FAG-201, or BG00012.
12. A medication history that precludes entry into the study.
13. Female subjects who are currently pregnant or breast-feeding.

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT00168701

Show 42 Study Locations

Sponsors and Collaborators

Biogen

Investigators

Principal Investigator:	Ludwig Kappos, Prof	Kantonsspital Basel
Study Director:	Gilmore O'Neill, MB, MRCPI, MMedSc	Biogen

More Information

No publications provided by Biogen

Additional publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Fox RJ, Kita M, Cohan SL, Henson LJ, Zambrano J, Scannevin RH, O'Gorman J, Novas M, Dawson KT, Phillips JT. BG-12 (dimethyl fumarate): a review of mechanism of action, efficacy, and safety. Curr Med Res Opin. 2014 Feb;30(2):251-62. doi: 10.1185/03007995.2013.849236. Epub 2013 Oct 22. Review.

relapsing-remitting multiple sclerosis: a multicentre, randomised, double-blind, placebo-controlled phase IIb study. Lancet. 2008 Oct 25;372(9648):1463-72. doi: 10.1016/S0140-6736(08)61619-0. Erratum in: Lancet. 2009 Apr 18;373(9672):1340.

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Keywords provided by Biogen:
Multiple Sclerosis
MRI

Additional relevant MeSH terms:

Multiple Sclerosis	Pathologic Processes
Multiple Sclerosis, Relapsing-Remitting	Dimethyl fumarate
Sclerosis	Dermatologic Agents
Autoimmune Diseases	Immunologic Factors
Autoimmune Diseases of the Nervous System	Immunosuppressive Agents
Demyelinating Autoimmune Diseases, CNS	Pharmacologic Actions
Demyelinating Diseases	Physiological Effects of Drugs
Immune System Diseases	Radiation-Sensitizing Agents
Nervous System Diseases	Therapeutic Uses

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