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Study to Compare Double-Dose Betaferon to the Approved Dose, for Patients With Early Secondary Progressive Multiple Sclerosis (SPMS)

This study has been terminated.

Sponsored by:	**Bayer**
Information provided by:	Bayer
ClinicalTrials.gov Identifier:	NCT00313976

Purpose

The purpose of the study is to evaluate if the higher dose can give greater efficacy without negative impact on the adverse event profile for patients with early secondary progressive Multiple Sclerosis (SPMS).

Condition	Intervention	Phase
Multiple Sclerosis	Drug: Interferon beta-1b (Betaferon/Betaseron, BAY86-5046)	Phase III

MedlinePlus related topics: MRI Scans Multiple Sclerosis

Drug Information available for: Interferons Interferon beta Interferon-beta Interferon beta-1b

U.S. FDA Resources

Study Type: Interventional
Study Design: Treatment, Randomized, Double Blind (Investigator, Outcomes Assessor), Dose Comparison, Parallel Assignment, Safety/Efficacy Study

Official Title: A Scandinavian, Randomized, Rater-Blinded Study of Single and Double-Dose Betaferon in Patients With Early Secondary Progressive Multiple Sclerosis

Further study details as provided by Bayer:

Primary Outcome Measures:

- Magnetic Resonance Imaging (MRI): T2-lesions [Time Frame: At week 104]

Secondary Outcome Measures:

- Further Magnetic Resonance Imaging (MRI) parameters [Time Frame: At week 104]
- Relapses [Time Frame: At week 104]
- Changes in Expanded Disability Status Score (EDSS) and Multiple Sclerosis Impact Scale (MSIS) [Time Frame: At week 104]
- Hospitalizations [Time Frame: At week 104]
- Neutralizing antibodies [Time Frame: At week 104]
- Adverse events [Time Frame: At week 104]

Enrollment: 0

Arms	Assigned Interventions
Arm 1: Experimental	Drug: Interferon beta-1b (Betaferon/Betaseron, BAY86-5046) 250 micrograms every other day, subcutaneously for 104 weeks
Arm 2: Experimental	Drug: Interferon beta-1b (Betaferon/Betaseron, BAY86-5046) 2x250 micrograms every other day, subcutaneously for 104 weeks

Detailed Description:

The study has previously been posted by Schering AG, Germany. Schering AG, Germany has been renamed to Bayer Schering Pharma AG, Germany.

Bayer Schering Pharma AG, Germany is the sponsor of the trial.

Eligibility

Ages Eligible for Study: 18 Years and older
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Diagnosis of MS for no less than one year and no longer than ten years
- Disease in the secondary progressive (SP) phase
- At least one relapse the last 3 years
- Treatment with an interferon for at least 6 months and with Betaferon for at least 3 months

Exclusion Criteria:

- Serious or acute heart disease

- Severe depression
- Serious or acute liver, kidney or bone marrow dysfunction
- Epilepsy not adequately treated
- Pregnancy or lactation
- Alcohol or drug abuse

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT00313976

Locations

Denmark

Copenhagen, Denmark, DK-2100
Holstebro, Denmark, DK-7500
Hillerød, Denmark, DK-3400
ask Contact, Denmark

Sweden

Stockholm, Sweden, 14186
Stockholm, Sweden, 171 76
Stockholm, Sweden, 11281

Sponsors and Collaborators

Bayer

Investigators

Study Director: Bayer Study Director Bayer

More Information

Click here and search for drug information provided by the FDA EXIT

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Responsible Party:	Bayer Schering Pharma AG (Therapeutic Area Head)
Study ID Numbers:	91449, EudraCT: 2005-001540-23, 309560
Study First Received:	April 11, 2006
Last Updated:	December 18, 2008
ClinicalTrials.gov Identifier:	NCT00313976 [history]
Health Authority:	Sweden: Medical Products Agency; Denmark: Danish Medicines Agency

Keywords provided by Bayer:

- Multiple Sclerosis
- Early secondary progressive Multiple Sclerosis

Study placed in the following topic categories:

- Autoimmune Diseases
- Multiple Sclerosis
- Demyelinating Diseases
- Interferons
- Interferon beta-1b
- Interferon-beta
- Neoplasm Metastasis
- Demyelinating Autoimmune Diseases, CNS
- Demyelinating diseases
- Sclerosis
- Autoimmune Diseases of the Nervous System
- Multiple Sclerosis, Chronic Progressive

Additional relevant MeSH terms:

- Anti-Infective Agents
- Pathologic Processes
- Immunologic Factors
- Immune System Diseases
- Antineoplastic Agents
- Therapeutic Uses
- Physiological Effects of Drugs
- Nervous System Diseases
- Adjuvants, Immunologic
- Antiviral Agents
- Pharmacologic Actions

ClinicalTrials.gov processed this record on January 16, 2009

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