Study Evaluating Rebif, Copaxone, and Tysabri for Active Multiple Sclerosis (SURPASS)

This study has been terminated.

(Due to significantly slower than expected enrollment, the Sponsor decided to terminate the study.)

Sponsor:
Biogen Idec

Collaborator:
Elan Pharmaceuticals

Information provided by (Responsible Party):
Biogen Idec

ClinicalTrials.gov Identifier:
NCT01058005

First received: January 26, 2010
Last updated: August 18, 2014
Last verified: August 2014
History of Changes

Full Text View | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Results First Received: July 23, 2014

Study Type:	Interventional
Study Design:	Allocation: Randomized; Intervention Model: Parallel Assignment; Masking: Open Label
Condition:	Relapsing Remitting Multiple Sclerosis
Interventions:	Drug: BG00002 (natalizumab) Drug: interferon beta-1a Drug: glatiramer acetate

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
No text entered.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
No text entered.

Reporting Groups

	Description
Natalizumab	300 mg intravenous injection every 4 weeks
Interferon Beta-1a	44 mcg subcutaneous injection 3 times per week
Glatiramer Acetate	20 mg subcutaneous injection once daily

Participant Flow: Overall Study

	Natalizumab	Interferon Beta-1a	Glatiramer Acetate

STARTED	38	25	21
Dosed With Study Treatment	36	22	17
COMPLETED	0	0	1
NOT COMPLETED	38	25	20
Adverse Event	0	2	1
Physician Decision	2	2	0
Withdrawal by Subject	4	5	11
Withdrawn Due to Study Termination	27	13	7
Reason Missing	5	3	1

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants who received at least 1 dose of study medication.

Reporting Groups

	Description
Natalizumab	300 mg intravenous injection every 4 weeks
Interferon Beta-1a	44 mcg subcutaneous injection 3 times per week
Glatiramer Acetate	20 mg subcutaneous injection once daily
Total	Total of all reporting groups

Baseline Measures

	Natalizumab	Interferon Beta-1a	Glatiramer Acetate	Total
Number of Participants [units: participants]	36	22	17	75
Age [units: years] Mean ± Standard Deviation	35.8 ± 9.51	39.0 ± 10.0	37.6 ± 13.16	37.1 ± 10.52
Gender [units: participants]				
Female	30	16	13	59
Male	6	6	4	16

Outcome Measures

1. Primary: Incidence of Treatment-emergent Serious Adverse Events (SAEs) [Time Frame: up to 108 Weeks]

Hide Outcome Measure 1

Measure Type	Primary

Measure Title	Incidence of Treatment-emergent Serious Adverse Events (SAEs)
Measure Description	An SAE was defined as any untoward medical occurrence that at any dose: results in death; in the view of the Investigator, places the subject at immediate risk of death (a life-threatening event; however, this does not include an event that, had it occurred in a more severe form, might have caused death); requires inpatient hospitalization or prolongation of existing hospitalization; results in persistent or significant disability/incapacity; or results in a congenital anomaly/birth defect. An SAE may also have been any other medically important event that, in the opinion of the Investigator, may jeopardize the subject or may require intervention to prevent one of the other outcomes listed in the definition above. See Adverse Events section below for further details.
Time Frame	up to 108 Weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Participants who received at least 1 dose of study medication.

Reporting Groups

	Description
Natalizumab	300 mg intravenous injection every 4 weeks
Interferon Beta-1a	44 mcg subcutaneous injection 3 times per week
Glatiramer Acetate	20 mg subcutaneous injection once daily

Measured Values

	Natalizumab	Interferon Beta-1a	Glatiramer Acetate
Number of Participants Analyzed [units: participants]	36	22	17
Incidence of Treatment-emergent Serious Adverse Events (SAEs) [units: participants]	1	1	0

No statistical analysis provided for Incidence of Treatment-emergent Serious Adverse Events (SAEs)

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Adverse events (AEs) were collected from the time of first dose of study treatment until the final clinic visit (96 weeks); serious adverse events (SAEs) were collected from the time of signed consent to 12 weeks after the last study visit (108 weeks).
Additional Description	No text entered.

Reporting Groups

	Description
Natalizumab	300 mg intravenous injection every 4 weeks
Interferon Beta-1a	44 mcg subcutaneous injection 3 times per week

Glatiramer Acetate	20 mg subcutaneous injection once daily

Serious Adverse Events

	Natalizumab	Interferon Beta-1a	Glatiramer Acetate
Total, serious adverse events			
# participants affected / at risk	1/36 (2.78%)	1/22 (4.55%)	0/17 (0.00%)
Infections and infestations			
Meningitis Herpes † 1			
# participants affected / at risk	0/36 (0.00%)	1/22 (4.55%)	0/17 (0.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Thyroid Cancer † 1			
# participants affected / at risk	1/36 (2.78%)	0/22 (0.00%)	0/17 (0.00%)
Nervous system disorders			
Cerebral Venous Thrombosis † 1			
# participants affected / at risk	0/36 (0.00%)	1/22 (4.55%)	0/17 (0.00%)

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 14.1

Other Adverse Events

Hide Other Adverse Events

Time Frame	Adverse events (AEs) were collected from the time of first dose of study treatment until the final clinic visit (96 weeks); serious adverse events (SAEs) were collected from the time of signed consent to 12 weeks after the last study visit (108 weeks).
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Natalizumab	300 mg intravenous injection every 4 weeks
Interferon Beta-1a	44 mcg subcutaneous injection 3 times per week
Glatiramer Acetate	20 mg subcutaneous injection once daily

Other Adverse Events

	Natalizumab	Interferon Beta-1a	Glatiramer Acetate
Total, other (not including serious) adverse events			

# participants affected / at risk	19/36 (52.78%)	12/22 (54.55%)	11/17 (64.71%)
Blood and lymphatic system disorders			
Lymphadenopathy † [1]			
# participants affected / at risk	1/36 (2.78%)	0/22 (0.00%)	1/17 (5.88%)
Anaemia Macrocytic † [1]			
# participants affected / at risk	0/36 (0.00%)	0/22 (0.00%)	1/17 (5.88%)
Ear and labyrinth disorders			
Vertigo † [1]			
# participants affected / at risk	1/36 (2.78%)	2/22 (9.09%)	1/17 (5.88%)
Eye disorders			
Vision Blurred † [1]			
# participants affected / at risk	1/36 (2.78%)	0/22 (0.00%)	1/17 (5.88%)
Vitreous Floaters † [1]			
# participants affected / at risk	0/36 (0.00%)	0/22 (0.00%)	1/17 (5.88%)
Gastrointestinal disorders			
Nausea † [1]			
# participants affected / at risk	6/36 (16.67%)	2/22 (9.09%)	1/17 (5.88%)
Vomiting † [1]			
# participants affected / at risk	3/36 (8.33%)	3/22 (13.64%)	0/17 (0.00%)
Constipation † [1]			
# participants affected / at risk	0/36 (0.00%)	0/22 (0.00%)	2/17 (11.76%)
Diarrhoea † [1]			
# participants affected / at risk	0/36 (0.00%)	1/22 (4.55%)	1/17 (5.88%)
Dysphagia † [1]			
# participants affected / at risk	0/36 (0.00%)	1/22 (4.55%)	1/17 (5.88%)
Gastrointestinal Disorder † [1]			
# participants affected / at risk	0/36 (0.00%)	0/22 (0.00%)	1/17 (5.88%)
Periodontal Disease † [1]			
# participants affected / at risk	0/36 (0.00%)	0/22 (0.00%)	1/17 (5.88%)
General disorders			
Fatigue † [1]			
# participants affected / at risk	4/36 (11.11%)	2/22 (9.09%)	3/17 (17.65%)
Gait Disturbance † [1]			
# participants affected / at risk	0/36 (0.00%)	2/22 (9.09%)	1/17 (5.88%)
Pyrexia † [1]			
# participants affected / at risk	2/36 (5.56%)	1/22 (4.55%)	0/17 (0.00%)
Injection Site Reaction † [1]			
# participants affected / at risk	0/36 (0.00%)	0/22 (0.00%)	2/17 (11.76%)
Influenza Like Illness † [1]			
# participants affected / at risk	0/36 (0.00%)	0/22 (0.00%)	1/17 (5.88%)

Injection Site Mass † 1			
# participants affected / at risk	0/36 (0.00%)	0/22 (0.00%)	1/17 (5.88%)
Injection Site Pruritus † 1			
# participants affected / at risk	0/36 (0.00%)	0/22 (0.00%)	1/17 (5.88%)
Injection Site Swelling † 1			
# participants affected / at risk	0/36 (0.00%)	0/22 (0.00%)	1/17 (5.88%)
Infections and infestations			
Urinary Tract Infection † 1			
# participants affected / at risk	5/36 (13.89%)	0/22 (0.00%)	0/17 (0.00%)
Bronchitis † 1			
# participants affected / at risk	2/36 (5.56%)	1/22 (4.55%)	1/17 (5.88%)
Nasopharyngitis † 1			
# participants affected / at risk	3/36 (8.33%)	1/22 (4.55%)	0/17 (0.00%)
Sinusitis † 1			
# participants affected / at risk	3/36 (8.33%)	0/22 (0.00%)	1/17 (5.88%)
Upper Respiratory Tract Infection † 1			
# participants affected / at risk	2/36 (5.56%)	1/22 (4.55%)	0/17 (0.00%)
Vulvovaginal Mycotic Infection † 1			
# participants affected / at risk	1/36 (2.78%)	0/22 (0.00%)	1/17 (5.88%)
Cystitis † 1			
# participants affected / at risk	0/36 (0.00%)	0/22 (0.00%)	1/17 (5.88%)
Gastritis Viral † 1			
# participants affected / at risk	0/36 (0.00%)	0/22 (0.00%)	1/17 (5.88%)
Gastroenteritis † 1			
# participants affected / at risk	0/36 (0.00%)	0/22 (0.00%)	1/17 (5.88%)
Herpes Zoster † 1			
# participants affected / at risk	0/36 (0.00%)	0/22 (0.00%)	1/17 (5.88%)
Hordeolum † 1			
# participants affected / at risk	0/36 (0.00%)	0/22 (0.00%)	1/17 (5.88%)
Influenza † 1			
# participants affected / at risk	0/36 (0.00%)	0/22 (0.00%)	1/17 (5.88%)
Tooth Infection † 1			
# participants affected / at risk	0/36 (0.00%)	0/22 (0.00%)	1/17 (5.88%)
Injury, poisoning and procedural complications			
Fall † 1			
# participants affected / at risk	0/36 (0.00%)	2/22 (9.09%)	1/17 (5.88%)
Contusion † 1			
# participants affected / at risk	0/36 (0.00%)	0/22 (0.00%)	1/17 (5.88%)
Exposure To Toxic Agent † 1			
# participants affected / at risk	0/36 (0.00%)	0/22 (0.00%)	1/17 (5.88%)
Tibia Fracture † 1			

# participants affected / at risk	0/36 (0.00%)	0/22 (0.00%)	1/17 (5.88%)
Investigations			
Heart Rate Increased † 1			
# participants affected / at risk	0/36 (0.00%)	0/22 (0.00%)	1/17 (5.88%)
Vitamin D Decreased † 1			
# participants affected / at risk	0/36 (0.00%)	0/22 (0.00%)	1/17 (5.88%)
Metabolism and nutrition disorders			
Fluid Retention † 1			
# participants affected / at risk	0/36 (0.00%)	0/22 (0.00%)	1/17 (5.88%)
Vitamin B12 Deficiency † 1			
# participants affected / at risk	0/36 (0.00%)	0/22 (0.00%)	1/17 (5.88%)
Musculoskeletal and connective tissue disorders			
Pain In Extremity † 1			
# participants affected / at risk	1/36 (2.78%)	1/22 (4.55%)	2/17 (11.76%)
Myalgia † 1			
# participants affected / at risk	1/36 (2.78%)	2/22 (9.09%)	0/17 (0.00%)
Muscle Spasms † 1			
# participants affected / at risk	0/36 (0.00%)	0/22 (0.00%)	2/17 (11.76%)
Muscle Fatigue † 1			
# participants affected / at risk	0/36 (0.00%)	0/22 (0.00%)	1/17 (5.88%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Uterine Leiomyoma † 1			
# participants affected / at risk	0/36 (0.00%)	0/22 (0.00%)	1/17 (5.88%)
Nervous system disorders			
Multiple Sclerosis Relapse † 1			
# participants affected / at risk	1/36 (2.78%)	3/22 (13.64%)	5/17 (29.41%)
Headache † 1			
# participants affected / at risk	5/36 (13.89%)	2/22 (9.09%)	1/17 (5.88%)
Paraesthesia † 1			
# participants affected / at risk	3/36 (8.33%)	3/22 (13.64%)	1/17 (5.88%)
Hypoaesthesia † 1			
# participants affected / at risk	1/36 (2.78%)	3/22 (13.64%)	0/17 (0.00%)
Migraine † 1			
# participants affected / at risk	2/36 (5.56%)	1/22 (4.55%)	1/17 (5.88%)
Dizziness † 1			
# participants affected / at risk	2/36 (5.56%)	1/22 (4.55%)	0/17 (0.00%)
Loss Of Proprioception † 1			
# participants affected / at risk	0/36 (0.00%)	0/22 (0.00%)	2/17 (11.76%)
Neuralgia † 1			
# participants affected / at risk	2/36 (5.56%)	0/22 (0.00%)	0/17 (0.00%)

Hyperaesthesia † 1			
# participants affected / at risk	0/36 (0.00%)	0/22 (0.00%)	1/17 (5.88%)
Hypertonia † 1			
# participants affected / at risk	0/36 (0.00%)	0/22 (0.00%)	1/17 (5.88%)
Memory Impairment † 1			
# participants affected / at risk	0/36 (0.00%)	0/22 (0.00%)	1/17 (5.88%)
Orthostatic Tremor † 1			
# participants affected / at risk	0/36 (0.00%)	0/22 (0.00%)	1/17 (5.88%)
Psychiatric disorders			
Anxiety † 1			
# participants affected / at risk	0/36 (0.00%)	2/22 (9.09%)	1/17 (5.88%)
Insomnia † 1			
# participants affected / at risk	0/36 (0.00%)	0/22 (0.00%)	1/17 (5.88%)
Stress † 1			
# participants affected / at risk	0/36 (0.00%)	0/22 (0.00%)	1/17 (5.88%)
Renal and urinary disorders			
Urinary Incontinence † 1			
# participants affected / at risk	1/36 (2.78%)	0/22 (0.00%)	1/17 (5.88%)
Micturition Urgency † 1			
# participants affected / at risk	0/36 (0.00%)	0/22 (0.00%)	1/17 (5.88%)
Respiratory, thoracic and mediastinal disorders			
Cough † 1			
# participants affected / at risk	2/36 (5.56%)	0/22 (0.00%)	0/17 (0.00%)
Oropharyngeal Pain † 1			
# participants affected / at risk	2/36 (5.56%)	0/22 (0.00%)	0/17 (0.00%)
Epistaxis † 1			
# participants affected / at risk	0/36 (0.00%)	0/22 (0.00%)	1/17 (5.88%)
Upper Respiratory Tract Congestion † 1			
# participants affected / at risk	0/36 (0.00%)	0/22 (0.00%)	1/17 (5.88%)
Skin and subcutaneous tissue disorders			
Alopecia † 1			
# participants affected / at risk	2/36 (5.56%)	0/22 (0.00%)	0/17 (0.00%)
Dermatitis Contact † 1			
# participants affected / at risk	0/36 (0.00%)	0/22 (0.00%)	1/17 (5.88%)
Pruritus † 1			
# participants affected / at risk	0/36 (0.00%)	0/22 (0.00%)	1/17 (5.88%)
Subcutaneous Nodule † 1			
# participants affected / at risk	0/36 (0.00%)	0/22 (0.00%)	1/17 (5.88%)

† Events were collected by systematic assessment

1 Term from vocabulary, MedDRA 14.1

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
Due to early termination of the study and the small size of the study population, there was insufficient power for efficacy and safety analyses. Only serious adverse events were to be captured and reported under the protocol.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.
There IS an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.
The agreement is: ☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is less than or equal to 60 days. The sponsor cannot require changes to the communication and cannot extend the embargo. ☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is more than 60 days but less than or equal to 180 days. The sponsor cannot require changes to the communication and cannot extend the embargo. Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed. ☑ Restriction Description: Our agreement is subject to confidentiality but generally the PI can publish, for noncommercial purposes only, results and methods of the trial, but no other Sponsor Confidential Information. PI must give Sponsor no less than 60 days to review any manuscript for a proposed publication and must delay publication for up to an additional 90 days thereafter if Sponsor needs to file any patent application to protect any of Sponsor's intellectual property contained in the proposed publication.

Results Point of Contact:

Name/Title: Biogen Idec Study Medical Director
Organization: Biogen Idec
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No publications provided

Responsible Party:	Biogen Idec
ClinicalTrials.gov Identifier:	NCT01058005 History of Changes
Other Study ID Numbers:	101MS325
Study First Received:	January 26, 2010
Results First Received:	July 23, 2014
Last Updated:	August 18, 2014
Health Authority:	Sweden: Medical Products Agency Spain: Spanish Agency of Medicines Italy: Ministry of Health Czech Republic: State Institute for Drug Control Poland: Ministry of Health Hungary: National Institute of Pharmacy Canada: Health Canada Latvia: State Agency of Medicines United States: Food and Drug Administration