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Trial record **1 of 1** for: 101MS205

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Treatment Interruption of Natalizumab (RESTORE)

This study has been completed.

Sponsor:
Biogen

Collaborator:
Elan Pharmaceuticals

Information provided by (Responsible Party):
Biogen

ClinicalTrials.gov Identifier:
NCT01071083

First received: February 17, 2010
Last updated: September 12, 2013
Last verified: November 2012
History of Changes

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Results First Received: October 25, 2012

Study Type:	Interventional
Study Design:	Allocation: Randomized; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Condition:	Relapsing Remitting Multiple Sclerosis
Interventions:	Drug: natalizumab Drug: interferon beta 1-a Drug: methylprednisolone Other: IV placebo 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
Date of first treatment: 31 March 2010. Date of study completion: 02 November 2011.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
175 subjects were enrolled, all 175 were randomized.

Reporting Groups

	Description
Intravenous Placebo	placebo matching natalizumab, intravenous every 4 weeks
Natalizumab	300 mg intravenous every 4 weeks
Interferon β-1a	30 ug intramuscular once per week
Glatiramer Acetate	20 mg subcutaneous once daily

Methylprednisolone	1000 mg intravenous every 4 weeks

Participant Flow: Overall Study

	Intravenous Placebo	Natalizumab	Interferon β-1a	Glatiramer Acetate	Methylprednisolone
STARTED	42	45	17	17	54
COMPLETED	35	43	12	15	46
NOT COMPLETED	7	2	5	2	8
Adverse Event	1	0	1	0	1
Withdrawal by Subject	3	0	2	0	3
Physician Decision	1	0	0	1	1
Early Rescue	1	0	0	0	1
Subject Moved	0	1	0	0	0
Images Not Usable (Motion)	0	1	0	0	0
Did Not Meet Eligibility Criteria	0	0	1	1	1
Did Not Want Per Protocol Treatment	0	0	1	0	1
Subject Refused to Continue	1	0	0	0	0

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.
No text entered.

Reporting Groups

	Description
Natalizumab	300 mg intravenous every 4 weeks
Intravenous Placebo	placebo matching natalizumab, intravenous every 4 weeks
Interferon β-1a	30 ug intramuscular once per week
Glatiramer Acetate	20 mg subcutaneous once daily
Methylprednisolone	1000 mg intravenous every 4 weeks
Total	Total of all reporting groups

Baseline Measures

	Natalizumab	Intravenous Placebo	Interferon β-1a	Glatiramer Acetate	Methylprednisolone	Total
Number of Participants [units: participants]	45	42	17	17	54	175
Age [units: Years] Mean (Standard Deviation)	41.2 (9.70)	40.0 (10.36)	45.1 (9.92)	44.1 (7.85)	40.1 (9.96)	41.2 (9.85)
Gender [units: Participants]						

Female	**37**	**31**	**14**	**14**	**39**	**135**
Male	**8**	**11**	**3**	**3**	**15**	**40**

Outcome Measures

Hide All Outcome Measures

1. Primary: Time Course to Return of Radiological and/or Clinical Evidence of Multiple Sclerosis Activity, as Measured by the Percentage of Subjects Who Met Magnetic Resonance Imaging (MRI) and/or Clinical Relapse Rescue Criteria. [Time Frame: 28 Weeks]

Measure Type	Primary
Measure Title	Time Course to Return of Radiological and/or Clinical Evidence of Multiple Sclerosis Activity, as Measured by the Percentage of Subjects Who Met Magnetic Resonance Imaging (MRI) and/or Clinical Relapse Rescue Criteria.
Measure Description	Rescue criteria were: 1) central reader MRI finding of 1 new gadolinium-enhancing (Gd+) lesion of >0.8 cubic centimeters in volume or 2 or more Gd+ lesions of any size 2) clinical relapse. Clinical relapse was new or recurrent neurological symptoms not associated with fever or infection, lasting at least 24 hours, as defined by: an increase of ≥1 grade in ≥2 functional scales of the Expanded Disability Status Scale (EDSS); an increase of ≥2 grades in 1 functional scale of the EDSS; or an increase of >0.5 in EDSS if the previous EDSS was ≤5.5, or ≥0.5 if the previous EDSS was >5.5
Time Frame	28 Weeks
Safety Issue	No

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.
Of the randomized subjects, data from 167 subjects were used in efficacy analyses. Eight subjects were excluded from the analyses: 3 subjects had major protocol deviations and 5 subjects discontinued study participation prior to Week 4 Visit.

Reporting Groups

	Description
Natalizumab	300 mg intravenous every 4 weeks
Intravenous Placebo	placebo matching natalizumab, intravenous every 4 weeks
Interferon β-1a	30 ug intramuscular once per week
Glatiramer Acetate	20 mg subcutaneous once daily
Methylprednisolone	1000 mg intravenous every 4 weeks

Measured Values

	Natalizumab	**Intravenous Placebo**	**Interferon β-1a**	**Glatiramer Acetate**	**Methylprednisolone**
Number of Participants Analyzed [units: participants]	**45**	**41**	**14**	**15**	**52**
Time Course to Return of Radiological and/or Clinical Evidence of Multiple Sclerosis Activity, as Measured by the Percentage of Subjects Who Met Magnetic Resonance Imaging (MRI) and/or Clinical Relapse Rescue Criteria. [units: Percentage of subjects meeting criteria]	**4.7**	**60.5**	**28.6**	**53.3**	**54.8**

No statistical analysis provided for Time Course to Return of Radiological and/or Clinical Evidence of Multiple Sclerosis Activity, as Measured by the Percentage of Subjects Who Met Magnetic Resonance Imaging (MRI) and/or Clinical Relapse Rescue Criteria.

2. Secondary: Time Course to Return of Radiological Activity, as Measured by the Percentage of Subjects Who Met Magnetic Resonance Imaging (MRI) Rescue Criteria. [Time Frame: 28 Weeks]

Measure Type	Secondary
Measure Title	Time Course to Return of Radiological Activity, as Measured by the Percentage of Subjects Who Met Magnetic Resonance Imaging (MRI) Rescue Criteria.
Measure Description	MRI rescue criteria were the presence of 1 new gadolinium-enhancing (Gd+) lesion of >0.8 cubic centimeters in volume or 2 or more Gd+ lesions of any size, according to the central MRI reader.
Time Frame	28 Weeks
Safety Issue	No

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.
Of the randomized subjects, data from 167 subjects were used in efficacy analyses. Eight subjects were excluded from the analyses: 3 subjects had major protocol deviations and 5 subjects discontinued study participation prior to Week 4 Visit.

Reporting Groups

	Description
Natalizumab	300 mg intravenous every 4 weeks
Intravenous Placebo	placebo matching natalizumab, intravenous every 4 weeks
Interferon β-1a	30 ug intramuscular once per week
Glatiramer Acetate	20 mg subcutaneous once daily
Methylprednisolone	1000 mg intravenous every 4 weeks

Measured Values

	Natalizumab	**Intravenous Placebo**	**Interferon β-1a**	**Glatiramer Acetate**	**Methylprednisolone**
Number of Participants Analyzed [units: participants]	**45**	**41**	**14**	**15**	**52**
Time Course to Return of Radiological Activity, as Measured by the Percentage of Subjects Who Met Magnetic Resonance Imaging (MRI) Rescue Criteria. [units: Percentage of subjects meeting criteria]	**0.0**	**52.5**	**8.3**	**49.7**	**46.1**

No statistical analysis provided for Time Course to Return of Radiological Activity, as Measured by the Percentage of Subjects Who Met Magnetic Resonance Imaging (MRI) Rescue Criteria.

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Reporting Groups

	Description
Intravenous Placebo	placebo matching natalizumab, intravenous every 4 weeks
Natalizumab	300 mg intravenous every 4 weeks

Interferon β-1a	30 ug intramuscular once per week
Glatiramer Acetate	20 mg subcutaneous once daily
Methylprednisolone	1000 mg intravenous every 4 weeks

Serious Adverse Events

	Intravenous Placebo	Natalizumab	Interferon β-1a	Glatiramer Acetate	Methylprednisolone
Total, serious adverse events					
# participants affected	1	1	1	1	1
General disorders					
Chest Pain †					
# participants affected / at risk	0/42 (0.00%)	1/45 (2.22%)	0/17 (0.00%)	0/17 (0.00%)	0/54 (0.00%)
# events	0	1	0	0	0
Infections and infestations					
Brain Abscess †					
# participants affected / at risk	0/42 (0.00%)	0/45 (0.00%)	0/17 (0.00%)	0/17 (0.00%)	1/54 (1.85%)
# events	0	0	0	0	1
Nervous system disorders					
Multiple Sclerosis †					
# participants affected / at risk	1/42 (2.38%)	0/45 (0.00%)	0/17 (0.00%)	0/17 (0.00%)	0/54 (0.00%)
# events	1	0	0	0	0
Multiple Sclerosis Relapse †					
# participants affected / at risk	0/42 (0.00%)	0/45 (0.00%)	0/17 (0.00%)	1/17 (5.88%)	0/54 (0.00%)
# events	0	0	0	2	0
Syncope †					
# participants affected / at risk	0/42 (0.00%)	0/45 (0.00%)	1/17 (5.88%)	0/17 (0.00%)	0/54 (0.00%)
# events	0	0	1	0	0
Presyncope †					
# participants affected / at risk	0/42 (0.00%)	0/45 (0.00%)	1/17 (5.88%)	0/17 (0.00%)	0/54 (0.00%)
# events	0	0	2	0	0

† Events were collected by systematic assessment

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Intravenous Placebo	placebo matching natalizumab, intravenous every 4 weeks
Natalizumab	300 mg intravenous every 4 weeks
Interferon β-1a	30 ug intramuscular once per week
Glatiramer Acetate	20 mg subcutaneous once daily
Methylprednisolone	1000 mg intravenous every 4 weeks

Other Adverse Events

	Intravenous Placebo	Natalizumab	Interferon β-1a	Glatiramer Acetate	Methylprednisolone
Total, other (not including serious) adverse events					
# participants affected	**35**	**38**	**15**	**15**	**42**
Blood and lymphatic system disorders					
LYMPHADENOPATHY †					
# participants affected / at risk	**0/42 (0.00%)**	**3/45 (6.67%)**	**0/17 (0.00%)**	**0/17 (0.00%)**	**1/54 (1.85%)**
Gastrointestinal disorders					
TONGUE CYST †					
# participants affected / at risk	**0/42 (0.00%)**	**0/45 (0.00%)**	**1/17 (5.88%)**	**0/17 (0.00%)**	**0/54 (0.00%)**
CONSTIPATION †					
# participants affected / at risk	**0/42 (0.00%)**	**1/45 (2.22%)**	**1/17 (5.88%)**	**0/17 (0.00%)**	**0/54 (0.00%)**
NAUSEA †					
# participants affected / at risk	**0/42 (0.00%)**	**1/45 (2.22%)**	**1/17 (5.88%)**	**0/17 (0.00%)**	**0/54 (0.00%)**
General disorders					
INFLUENZA LIKE ILLNESS †					
# participants affected / at risk	**0/42 (0.00%)**	**0/45 (0.00%)**	**5/17 (29.41%)**	**1/17 (5.88%)**	**0/54 (0.00%)**
GAIT DISTURBANCE †					
# participants affected / at risk	**0/42 (0.00%)**	**0/45 (0.00%)**	**0/17 (0.00%)**	**1/17 (5.88%)**	**0/54 (0.00%)**
INJECTION SITE HAEMATOMA †					
# participants affected / at risk	**0/42 (0.00%)**	**0/45 (0.00%)**	**0/17 (0.00%)**	**1/17 (5.88%)**	**0/54 (0.00%)**
ASTHENIA †					
# participants affected / at risk	**0/42 (0.00%)**	**0/45 (0.00%)**	**2/17 (11.76%)**	**0/17 (0.00%)**	**0/54 (0.00%)**
INJECTION SITE URTICARIA †					
# participants affected / at risk	**0/42 (0.00%)**	**0/45 (0.00%)**	**0/17 (0.00%)**	**1/17 (5.88%)**	**0/54 (0.00%)**
FATIGUE †					
# participants affected / at risk	**6/42 (14.29%)**	**2/45 (4.44%)**	**1/17 (5.88%)**	**2/17 (11.76%)**	**2/54 (3.70%)**
INJECTION SITE PAIN †					
# participants affected / at risk	**0/42 (0.00%)**	**0/45 (0.00%)**	**0/17 (0.00%)**	**1/17 (5.88%)**	**0/54 (0.00%)**
Immune system disorders					
DRUG HYPERSENSITIVITY †					
# participants affected / at risk	**0/42 (0.00%)**	**1/45 (2.22%)**	**1/17 (5.88%)**	**0/17 (0.00%)**	**0/54 (0.00%)**
Infections and infestations					
URINARY TRACT INFECTION †					
# participants affected / at risk	**5/42 (11.90%)**	**1/45 (2.22%)**	**2/17 (11.76%)**	**1/17 (5.88%)**	**2/54 (3.70%)**
INFLUENZA †					

# participants affected / at risk	1/42 (2.38%)	1/45 (2.22%)	0/17 (0.00%)	0/17 (0.00%)	3/54 (5.56%)
VULVOVAGINAL CANDIDIASIS †					
# participants affected / at risk	0/42 (0.00%)	0/45 (0.00%)	0/17 (0.00%)	1/17 (5.88%)	0/54 (0.00%)
UPPER RESPIRATORY TRACT INFECTION †					
# participants affected / at risk	6/42 (14.29%)	3/45 (6.67%)	0/17 (0.00%)	3/17 (17.65%)	6/54 (11.11%)
NASOPHARYNGITIS †					
# participants affected / at risk	5/42 (11.90%)	11/45 (24.44%)	4/17 (23.53%)	1/17 (5.88%)	5/54 (9.26%)
FUNGAL SKIN INFECTION †					
# participants affected / at risk	0/42 (0.00%)	0/45 (0.00%)	1/17 (5.88%)	0/17 (0.00%)	0/54 (0.00%)
PYELONEPHRITIS †					
# participants affected / at risk	0/42 (0.00%)	0/45 (0.00%)	0/17 (0.00%)	1/17 (5.88%)	0/54 (0.00%)
Injury, poisoning and procedural complications					
INCISION SITE PAIN †					
# participants affected / at risk	0/42 (0.00%)	0/45 (0.00%)	1/17 (5.88%)	0/17 (0.00%)	0/54 (0.00%)
POST LUMBAR PUNCTURE SYNDROME †					
# participants affected / at risk	1/42 (2.38%)	0/45 (0.00%)	2/17 (11.76%)	0/17 (0.00%)	2/54 (3.70%)
CONCUSSION †					
# participants affected / at risk	0/42 (0.00%)	0/45 (0.00%)	0/17 (0.00%)	1/17 (5.88%)	0/54 (0.00%)
LACERATION †					
# participants affected / at risk	0/42 (0.00%)	0/45 (0.00%)	0/17 (0.00%)	1/17 (5.88%)	1/54 (1.85%)
FALL †					
# participants affected / at risk	2/42 (4.76%)	1/45 (2.22%)	1/17 (5.88%)	1/17 (5.88%)	0/54 (0.00%)
CONTUSION †					
# participants affected / at risk	1/42 (2.38%)	0/45 (0.00%)	1/17 (5.88%)	0/17 (0.00%)	0/54 (0.00%)
Investigations					
BLOOD GLUCOSE INCREASED †					
# participants affected / at risk	0/42 (0.00%)	0/45 (0.00%)	0/17 (0.00%)	1/17 (5.88%)	0/54 (0.00%)
DRUG SPECIFIC ANTIBODY PRESENT †					
# participants affected / at risk	0/42 (0.00%)	0/45 (0.00%)	1/17 (5.88%)	0/17 (0.00%)	0/54 (0.00%)
PROTEIN URINE PRESENT †					
# participants affected / at risk	0/42 (0.00%)	1/45 (2.22%)	0/17 (0.00%)	1/17 (5.88%)	0/54 (0.00%)
ALANINE AMINOTRANSFERASE INCREASED †					
# participants affected / at risk	0/42 (0.00%)	0/45 (0.00%)	1/17 (5.88%)	0/17 (0.00%)	0/54 (0.00%)
GAMMA-GLUTAMYLTRANSFERASE INCREASED †					
# participants affected / at risk	0/42 (0.00%)	0/45 (0.00%)	1/17 (5.88%)	0/17 (0.00%)	0/54 (0.00%)
WHITE BLOOD CELLS URINE POSITIVE †					
# participants affected / at risk	0/42 (0.00%)	0/45 (0.00%)	0/17 (0.00%)	1/17 (5.88%)	0/54 (0.00%)
LYMPHOCYTE MORPHOLOGY ABNORMAL †					
# participants affected / at risk	0/42 (0.00%)	0/45 (0.00%)	0/17 (0.00%)	1/17 (5.88%)	0/54 (0.00%)

EOSINOPHIL COUNT INCREASED †					
# participants affected / at risk	0/42 (0.00%)	0/45 (0.00%)	1/17 (5.88%)	0/17 (0.00%)	0/54 (0.00%)
Metabolism and nutrition disorders					
FOLATE DEFICIENCY †					
# participants affected / at risk	0/42 (0.00%)	0/45 (0.00%)	1/17 (5.88%)	0/17 (0.00%)	0/54 (0.00%)
IRON DEFICIENCY †					
# participants affected / at risk	0/42 (0.00%)	0/45 (0.00%)	1/17 (5.88%)	0/17 (0.00%)	0/54 (0.00%)
VITAMIN D DEFICIENCY †					
# participants affected / at risk	0/42 (0.00%)	0/45 (0.00%)	0/17 (0.00%)	1/17 (5.88%)	0/54 (0.00%)
DEHYDRATION †					
# participants affected / at risk	0/42 (0.00%)	1/45 (2.22%)	0/17 (0.00%)	1/17 (5.88%)	0/54 (0.00%)
Musculoskeletal and connective tissue disorders					
BACK PAIN †					
# participants affected / at risk	1/42 (2.38%)	2/45 (4.44%)	0/17 (0.00%)	0/17 (0.00%)	3/54 (5.56%)
MUSCLE SPASMS †					
# participants affected / at risk	0/42 (0.00%)	0/45 (0.00%)	2/17 (11.76%)	1/17 (5.88%)	0/54 (0.00%)
MUSCULAR WEAKNESS †					
# participants affected / at risk	4/42 (9.52%)	2/45 (4.44%)	0/17 (0.00%)	0/17 (0.00%)	1/54 (1.85%)
PAIN IN EXTREMITY †					
# participants affected / at risk	1/42 (2.38%)	3/45 (6.67%)	0/17 (0.00%)	2/17 (11.76%)	1/54 (1.85%)
ARTHRALGIA †					
# participants affected / at risk	2/42 (4.76%)	1/45 (2.22%)	0/17 (0.00%)	1/17 (5.88%)	2/54 (3.70%)
JOINT STIFFNESS †					
# participants affected / at risk	0/42 (0.00%)	0/45 (0.00%)	1/17 (5.88%)	1/17 (5.88%)	0/54 (0.00%)
Nervous system disorders					
SYNCOPE †					
# participants affected / at risk	0/42 (0.00%)	0/45 (0.00%)	1/17 (5.88%)	0/17 (0.00%)	1/54 (1.85%)
MEMORY IMPAIRMENT †					
# participants affected / at risk	2/42 (4.76%)	0/45 (0.00%)	1/17 (5.88%)	0/17 (0.00%)	0/54 (0.00%)
HYPOAESTHESIA †					
# participants affected / at risk	2/42 (4.76%)	3/45 (6.67%)	1/17 (5.88%)	1/17 (5.88%)	0/54 (0.00%)
HYPERREFLEXIA †					
# participants affected / at risk	0/42 (0.00%)	0/45 (0.00%)	1/17 (5.88%)	0/17 (0.00%)	0/54 (0.00%)
COGNITIVE DISORDER †					
# participants affected / at risk	0/42 (0.00%)	0/45 (0.00%)	0/17 (0.00%)	1/17 (5.88%)	0/54 (0.00%)
ANTICHOLINERGIC SYNDROME †					
# participants affected / at risk	0/42 (0.00%)	0/45 (0.00%)	0/17 (0.00%)	1/17 (5.88%)	0/54 (0.00%)
MULTIPLE SCLEROSIS RELAPSE †					
# participants affected / at risk	8/42 (19.05%)	2/45 (4.44%)	4/17 (23.53%)	4/17 (23.53%)	11/54 (20.37%)
NEURALGIA †					
# participants affected / at risk	0/42 (0.00%)	0/45 (0.00%)	0/17 (0.00%)	1/17 (5.88%)	0/54 (0.00%)
DIZZINESS †					
# participants affected / at risk	0/42 (0.00%)	3/45 (6.67%)	0/17 (0.00%)	0/17 (0.00%)	0/54 (0.00%)
MIGRAINE †					

# participants affected / at risk	0/42 (0.00%)	0/45 (0.00%)	0/17 (0.00%)	1/17 (5.88%)	0/54 (0.00%)
LHERMITTE'S SIGN †					
# participants affected / at risk	0/42 (0.00%)	0/45 (0.00%)	0/17 (0.00%)	1/17 (5.88%)	0/54 (0.00%)
BURNING FEET SYNDROME †					
# participants affected / at risk	0/42 (0.00%)	0/45 (0.00%)	1/17 (5.88%)	0/17 (0.00%)	0/54 (0.00%)
HEADACHE †					
# participants affected / at risk	3/42 (7.14%)	8/45 (17.78%)	1/17 (5.88%)	1/17 (5.88%)	3/54 (5.56%)
PRESYNCOPE †					
# participants affected / at risk	0/42 (0.00%)	0/45 (0.00%)	1/17 (5.88%)	0/17 (0.00%)	0/54 (0.00%)
DYSGEUSIA †					
# participants affected / at risk	0/42 (0.00%)	0/45 (0.00%)	1/17 (5.88%)	0/17 (0.00%)	0/54 (0.00%)
PARAESTHESIA †					
# participants affected / at risk	3/42 (7.14%)	3/45 (6.67%)	0/17 (0.00%)	0/17 (0.00%)	0/54 (0.00%)
BALANCE DISORDER †					
# participants affected / at risk	1/42 (2.38%)	0/45 (0.00%)	0/17 (0.00%)	1/17 (5.88%)	0/54 (0.00%)
Psychiatric disorders					
SLEEP DISORDER †					
# participants affected / at risk	0/42 (0.00%)	0/45 (0.00%)	1/17 (5.88%)	0/17 (0.00%)	3/54 (5.56%)
HALLUCINATION, VISUAL †					
# participants affected / at risk	0/42 (0.00%)	0/45 (0.00%)	0/17 (0.00%)	1/17 (5.88%)	0/54 (0.00%)
PANIC ATTACK †					
# participants affected / at risk	0/42 (0.00%)	0/45 (0.00%)	0/17 (0.00%)	1/17 (5.88%)	0/54 (0.00%)
ANXIETY †					
# participants affected / at risk	2/42 (4.76%)	1/45 (2.22%)	1/17 (5.88%)	0/17 (0.00%)	1/54 (1.85%)
DEPRESSION †					
# participants affected / at risk	2/42 (4.76%)	1/45 (2.22%)	1/17 (5.88%)	0/17 (0.00%)	0/54 (0.00%)
Reproductive system and breast disorders					
BREAST CYST †					
# participants affected / at risk	0/42 (0.00%)	1/45 (2.22%)	1/17 (5.88%)	0/17 (0.00%)	0/54 (0.00%)
Respiratory, thoracic and mediastinal disorders					
DYSPNOEA †					
# participants affected / at risk	0/42 (0.00%)	0/45 (0.00%)	0/17 (0.00%)	1/17 (5.88%)	0/54 (0.00%)
OROPHARYNGEAL PAIN †					
# participants affected / at risk	0/42 (0.00%)	0/45 (0.00%)	1/17 (5.88%)	0/17 (0.00%)	3/54 (5.56%)
INCREASED UPPER AIRWAY SECRETION †					
# participants affected / at risk	0/42 (0.00%)	0/45 (0.00%)	0/17 (0.00%)	1/17 (5.88%)	0/54 (0.00%)
SINUS CONGESTION †					
# participants affected / at risk	0/42 (0.00%)	0/45 (0.00%)	1/17 (5.88%)	0/17 (0.00%)	0/54 (0.00%)
PRODUCTIVE COUGH †					
# participants affected / at risk	0/42 (0.00%)	0/45 (0.00%)	1/17 (5.88%)	0/17 (0.00%)	0/54 (0.00%)
Skin and subcutaneous tissue disorders					
RASH †					
# participants affected / at risk	0/42 (0.00%)	1/45 (2.22%)	1/17 (5.88%)	0/17 (0.00%)	0/54 (0.00%)

ECZEMA †					
# participants affected / at risk	**0/42 (0.00%)**	**0/45 (0.00%)**	**1/17 (5.88%)**	**0/17 (0.00%)**	**0/54 (0.00%)**
SKIN LESION †					
# participants affected / at risk	**0/42 (0.00%)**	**0/45 (0.00%)**	**0/17 (0.00%)**	**1/17 (5.88%)**	**0/54 (0.00%)**
Vascular disorders					
HYPERTENSION †					
# participants affected / at risk	**0/42 (0.00%)**	**0/45 (0.00%)**	**1/17 (5.88%)**	**0/17 (0.00%)**	**0/54 (0.00%)**
HYPOTENSION †					
# participants affected / at risk	**0/42 (0.00%)**	**0/45 (0.00%)**	**1/17 (5.88%)**	**0/17 (0.00%)**	**0/54 (0.00%)**

† Events were collected by systematic assessment

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
No text entered.

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:** The provisions of our agreement are 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 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:

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No publications provided by Biogen

Publications automatically indexed to this study:

Nakamura K, Brown RA, Narayanan S, Collins DL, Arnold DL; Alzheimer's Disease Neuroimaging Initiative. Diurnal fluctuations in brain volume: Statistical analyses of MRI from large populations. Neuroimage. 2015 Sep;118:126-32. doi: 10.1016/j.neuroimage.2015.05.077. Epub 2015 Jun 3.

Responsible Party:	Biogen
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Other Study ID Numbers:	**101MS205**
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