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Trial record **2 of 2** for: CFTY720D2324

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Disease Control and Safety in Patients With Relapsing Remitting Multiple Sclerosis (RRMS) Switching From Natalizumab to Fingolimod (TOFIINGO)

This study has been terminated.

(Based on recent publications, determination of natalizumub washout period was no longer relevant.)

Sponsor:
Novartis Pharmaceuticals

Information provided by (Responsible Party):
Novartis (Novartis Pharmaceuticals)

ClinicalTrials.gov Identifier:
NCT01499667

First received: August 18, 2011
Last updated: August 6, 2014
Last verified: August 2014
History of Changes

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Results First Received: November 25, 2013

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Outcomes Assessor); Primary Purpose: Treatment
Condition:	Relapsing Remitting Multiple Sclerosis (RRMS)
Interventions:	Drug: Fingolimod Drug: Placebo

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
Of the 158 patients screened, 142 patients were randomized.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
142 Participants were randomized to 3 washout groups in a ratio of 1:1:1

Reporting Groups

	Description
8-week Washout + Fingolimod (FTY720)	8-week washout (8 weeks no treatment) followed by 24 weeks of treatment with fingolimod 0.5mg once a day
12-week Washout + Fingolimod (FTY720)	12-week washout (8 weeks no treatment and 4 weeks placebo) followed by 20 weeks of treatment with fingolimod 0.5mg once a day
16-week Washout + Fingolimod (FTY720)	16-week washout (8 weeks no treatment and 8 weeks placebo) followed by 16 weeks of treatment with fingolimod 0.5mg once a day

Participant Flow: Overall Study

	8-week Washout + Fingolimod (FTY720)	12-week Washout + Fingolimod (FTY720)	16-week Washout + Fingolimod (FTY720)
STARTED	**50** [1]	**42**	**50**
Full Analysis Set (FAS)	**49** [2]	**42**	**50**
Modified Full Analysis	**41** [3]	**29**	**39**

Set			
COMPLETED	**41**	**31**	**40**
NOT COMPLETED	**9**	**11**	**10**
administrative problems	**4**	**5**	**5**
Protocol Violation	**1**	**3**	**2**
Adverse Event	**0**	**2**	**2**
Withdrawal by Subject	**2**	**1**	**1**
Lack of Efficacy	**2**	**0**	**0**

[1] Started" indicates randomized as well as safety population.
[2] One randomized patient did not receive natalizumub at screening, which was a requirement for FAS.
[3] mFAS included all FAS patients who completed 8 wks of fingolimod treatment with MRI scan

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.
Randomized set includes all subjects who receive a randomization number, regardless of whether or not they receive study medication.

Reporting Groups

	Description
8-week Washout + Fingolimod (FTY720)	8-week washout (8 weeks no treatment) followed by 24 weeks of treatment with fingolimod 0.5mg once a day
12-week Washout + Fingolimod (FTY720)	12-week washout (8 weeks no treatment and 4 weeks placebo) followed by 20 weeks of treatment

	with fingolimod 0.5mg once a day
16-week Washout + Fingolimod (FTY720)	16-week washout (8 weeks no treatment and 8 weeks placebo) followed by 16 weeks of treatment with fingolimod
Total	Total of all reporting groups

Baseline Measures

	8-week Washout + Fingolimod (FTY720)	12-week Washout + Fingolimod (FTY720)	16-week Washout + Fingolimod (FTY720)	Total
Number of Participants [units: participants]	**50**	**42**	**50**	**142**
Age [units: Years] Mean (Standard Deviation)	**41.2 (10.102)**	**41.9 (7.445)**	**41.8 (8.552)**	**41.6 (8.780)**
Gender [units: Participants]				
Female	**39**	**21**	**32**	**92**
Male	**11**	**21**	**18**	**50**

Outcome Measures

Hide All Outcome Measures

1. Primary: Number of Active (New or Newly Enlarging) T2 Lesions From the Last Natalizumab Infusion (Baseline) Through 8 Weeks of Fingolimod Treatment [Time Frame: Number of active T2 lesions from last natalizumab dose through 8 weeks of fingolimod treatment]

Measure Type	Primary

Measure Title	Number of Active (New or Newly Enlarging) T2 Lesions From the Last Natalizumab Infusion (Baseline) Through 8 Weeks of Fingolimod Treatment
Measure Description	Active lesions were measured on brain MRI scans, performed at week 8, compared to the prior scan. The primary variable was analyzed by fitting a negative binomial regression model adjusted for washout group.
Time Frame	Number of active T2 lesions from last natalizumab dose through 8 weeks of fingolimod treatment
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.
The modified Full Analysis Set (mFAS) included all patients in the Full Analysis Set who completed 8 weeks of fingolimod treatment and provided an MRI scan at this time point. The analysis of primary variable was performed on the mFAS.

Reporting Groups

	Description
8-week Washout + Fingolimod (FTY720)	8-week washout (8 weeks no treatment) followed by 24 weeks of treatment with fingolimod 0.5mg once a day
12-week Washout + Fingolimod (FTY720)	12-week washout (8 weeks no treatment and 4 weeks placebo) followed by 20 weeks of treatment with fingolimod 0.5mg once a day
16-week Washout + Fingolimod (FTY720)	16-week washout (8 weeks no treatment and 8 weeks placebo) followed by 16 weeks of treatment with fingolimod 0.5mg once a day

Measured Values

	8-week Washout + Fingolimod (FTY720)	**12-week Washout + Fingolimod (FTY720)**	**16-week Washout + Fingolimod (FTY720)**
Number of Participants Analyzed [units: participants]	**41**	**29**	**39**
Number of Active (New or Newly Enlarging) T2 Lesions From the Last			

Natalizumab Infusion (Baseline) Through 8 Weeks of Fingolimod Treatment [units: Count of Active T2 Lesions] Mean (Standard Deviation)	**2.1 (7.24)**	**1.7 (3.78)**	**8.2 (16.81)**

No statistical analysis provided for Number of Active (New or Newly Enlarging) T2 Lesions From the Last Natalizumab Infusion (Baseline) Through 8 Weeks of Fingolimod Treatment

2. Secondary: Number of Active (New or Newly Enlarging) T2 Lesions From the Last Natalizumab Infusion (Baseline) up to the Initiation of Fingolimod Treatment [Time Frame: 8, 12 and 16 weeks (number of active T2 lesions during the washout period only)]

Measure Type	Secondary
Measure Title	Number of Active (New or Newly Enlarging) T2 Lesions From the Last Natalizumab Infusion (Baseline) up to the Initiation of Fingolimod Treatment
Measure Description	Lesions were measured by MRIs and the number of active (new or newly enlarging) T2 lesions was calculated from baseline to beginning of treatment.
Time Frame	8, 12 and 16 weeks (number of active T2 lesions during the washout period only)
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.
The Full Analysis Set (FAS) included all randomized patients who had at least one recorded dose of natalizumab at the Week 0 visit, analyzed according to the washout group assigned at randomization

Reporting Groups

	Description
8-week Washout + Fingolimod (FTY720)	8-week washout (8 weeks no treatment) followed by 24 weeks of treatment with fingolimod 0.5mg once a day

12-week Washout + Fingolimod (FTY720)	12-week washout (8 weeks no treatment and 4 weeks placebo) followed by 20 weeks of treatment with fingolimod 0.5mg once a day
16-week Washout + Fingolimod (FTY720)	16-week washout (8 weeks no treatment and 8 weeks placebo) followed by 16 weeks of treatment with fingolimod 0.5mg once a day

Measured Values

	8-week Washout + Fingolimod (FTY720)	12-week Washout + Fingolimod (FTY720)	16-week Washout + Fingolimod (FTY720)
Number of Participants Analyzed [units: participants]	**49**	**42**	**50**
Number of Active (New or Newly Enlarging) T2 Lesions From the Last Natalizumab Infusion (Baseline) up to the Initiation of Fingolimod Treatment [units: Count of active T2 lesions] Mean (Standard Deviation)	**0.4 (2.71)**	**2.1 (11.15)**	**3.6 (7.54)**

No statistical analysis provided for Number of Active (New or Newly Enlarging) T2 Lesions From the Last Natalizumab Infusion (Baseline) up to the Initiation of Fingolimod Treatment

3. Secondary: Number of Active (New or Newly Enlarging) T2 Lesions During the First 8 Weeks of Fingolimod Treatment [Time Frame: Number of active T2 lesions during 8 wks of fingolimod treatment]

Measure Type	Secondary
Measure Title	Number of Active (New or Newly Enlarging) T2 Lesions During the First 8 Weeks of Fingolimod Treatment
Measure Description	Lesions were measured by MRIs and the number of active (new or newly enlarging) T2 lesions was calculated for first 8 weeks of fingolimod treatment.
Time Frame	Number of active T2 lesions during 8 wks of fingolimod treatment

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.
The Full Analysis Set (FAS) included all randomized patients who had at least one recorded dose of natalizumab at the Week 0 visit, analyzed according to the washout group assigned at randomization

Reporting Groups

	Description
8-week Washout + Fingolimod (FTY720)	8-week washout (8 weeks no treatment) followed by 24 weeks of treatment with fingolimod 0.5mg once a day
12-week Washout + Fingolimod (FTY720)	12-week washout (8 weeks no treatment and 4 weeks placebo) followed by 20 weeks of treatment with fingolimod 0.5mg once a day
16-week Washout + Fingolimod (FTY720)	16-week washout (8 weeks no treatment and 8 weeks placebo) followed by 16 weeks of treatment with fingolimod 0.5mg once a day

Measured Values

	8-week Washout + Fingolimod (FTY720)	**12-week Washout + Fingolimod (FTY720)**	**16-week Washout + Fingolimod (FTY720)**
Number of Participants Analyzed [units: participants]	**49**	**42**	**50**
Number of Active (New or Newly Enlarging) T2 Lesions During the First 8 Weeks of Fingolimod Treatment [units: Count of Active T2 Lesions] Mean (Standard Deviation)	**1.5 (4.56)**	**2.1 (5.50)**	**4.2 (10.24)**

No statistical analysis provided for Number of Active (New or Newly Enlarging) T2 Lesions During the First 8 Weeks of Fingolimod Treatment

4. Secondary: Number of Active (New or Newly Enlarging) T2 Lesions During the 24 Weeks After the Last Natalizumab Infusion (Baseline) [Time Frame: Baseline up to 24 weeks]

Measure Type	Secondary
Measure Title	Number of Active (New or Newly Enlarging) T2 Lesions During the 24 Weeks After the Last Natalizumab Infusion (Baseline)
Measure Description	Lesions will be measured by MRIs and the number of active (new or newly enlarging) T2 lesions will be calculated for 24 weeks from baseline.
Time Frame	Baseline up to 24 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.
The Full Analysis Set (FAS) included all randomized patients who had at least one recorded dose of natalizumab at the Week 0 visit, analyzed according to the washout group assigned at randomization

Reporting Groups

	Description
8-week Washout + Fingolimod (FTY720)	8-week washout (8 weeks no treatment) followed by 24 weeks of treatment with fingolimod 0.5mg once a day
12-week Washout + Fingolimod (FTY720)	12-week washout (8 weeks no treatment and 4 weeks placebo) followed by 20 weeks of treatment with fingolimod 0.5mg once a day
16-week Washout + Fingolimod (FTY720)	16-week washout (8 weeks no treatment and 8 weeks placebo) followed by 16 weeks of treatment with fingolimod 0.5mg once a day

Measured Values

	8-week Washout +		

	Fingolimod (FTY720)	12-week Washout + Fingolimod (FTY720)	16-week Washout + Fingolimod (FTY720)
Number of Participants Analyzed [units: participants]	**49**	**42**	**50**
Number of Active (New or Newly Enlarging) T2 Lesions During the 24 Weeks After the Last Natalizumab Infusion (Baseline) [units: Count of Active T2 Lesions] Mean (Standard Deviation)	**3.2 (10.07)**	**4.4 (16.01)**	**7.7 (16.28)**

No statistical analysis provided for Number of Active (New or Newly Enlarging) T2 Lesions During the 24 Weeks After the Last Natalizumab Infusion (Baseline)

5. Secondary: Change From Baseline in Expanded Disability Status Scale (EDSS) by Washout Group [Time Frame: Baseline to week 16 and week 32]

Measure Type	Secondary
Measure Title	Change From Baseline in Expanded Disability Status Scale (EDSS) by Washout Group
Measure Description	Kurtzke's Expanded Disability Status Scale (EDSS) measures the changes in neurologic impairment, either chronic (progression over time), or acute (MS relapses). The EDSS steps range from 0 (normal) to 10 (death due to MS). Relapse severity is assessed based on severity of neurologic impairment as evaluated using the EDSS.
Time Frame	Baseline to week 16 and week 32
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.
The Full Analysis Set (FAS) included all randomized patients who had at least one recorded dose of natalizumab at the Week 0 visit, analyzed according to the washout group assigned at randomization.

Reporting Groups

	Description
8-week Washout + Fingolimod (FTY720)	8-week washout (8 weeks no treatment) followed by 24 weeks of treatment with fingolimod 0.5mg once a day
12-week Washout + Fingolimod (FTY720)	12-week washout (8 weeks no treatment and 4 weeks placebo) followed by 20 weeks of treatment with fingolimod 0.5mg once a day
16-week Washout + Fingolimod (FTY720)	16-week washout (8 weeks no treatment and 8 weeks placebo) followed by 16 weeks of treatment with fingolimod 0.5mg once a day

Measured Values

	8-week Washout + Fingolimod (FTY720)	12-week Washout + Fingolimod (FTY720)	16-week Washout + Fingolimod (FTY720)
Number of Participants Analyzed [units: participants]	**49**	**42**	**50**
Change From Baseline in Expanded Disability Status Scale (EDSS) by Washout Group [units: Units on a scale] Mean (Standard Deviation)			
Week 16 (n=40, 33, 39)	**0.11 (0.330)**	**-0.03 (0.529)**	**0.23 (0.706)**
Week 32 (n= 40,30,39)	**0.11 (0.625)**	**-0.13 (0.524)**	**0.08 (0.748)**

No statistical analysis provided for Change From Baseline in Expanded Disability Status Scale (EDSS) by Washout Group

6. Secondary: Cumulative Number of Gadolinium-enhancing T1 Lesions From the Last Natalizumab Infusion [Time Frame: 8 weeks and 24 weeks]

Measure Type	Secondary

Measure Title	Cumulative Number of Gadolinium-enhancing T1 Lesions From the Last Natalizumab Infusion
Measure Description	Gadolinium-enhancing lesions will be measured on post-contrast T1-weighted brain MRI scans
Time Frame	8 weeks and 24 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.
The Full Analysis Set (FAS) included all randomized patients who had at least one recorded dose of natalizumab at the Week 0 visit, analyzed according to the washout group assigned at randomization.

Reporting Groups

	Description
8-week Washout + Fingolimod (FTY720)	8-week washout (8 weeks no treatment) followed by 24 weeks of treatment with fingolimod 0.5mg once a day
12-week Washout + Fingolimod (FTY720)	12-week washout (8 weeks no treatment and 4 weeks placebo) followed by 20 weeks of treatment with fingolimod 0.5mg once a day
16-week Washout + Fingolimod (FTY720)	16-week washout (8 weeks no treatment and 8 weeks placebo) followed by 16 weeks of treatment with fingolimod 0.5mg once a day

Measured Values

	8-week Washout + Fingolimod (FTY720)	**12-week Washout + Fingolimod (FTY720)**	**16-week Washout + Fingolimod (FTY720)**
Number of Participants Analyzed [units: participants]	**49**	**42**	**50**
Cumulative Number of Gadolinium-enhancing T1 Lesions From the Last Natalizumab Infusion [units: Number of Gd enhanced T1 Lesions] Mean (Standard Deviation)			

Week 8 (n=1,1,0)	**25.0 (0)**	**2.0 (0)**	**NA [1]**
Week 24 (n=10,12,21)	**6.3 (9.45)**	**3.4 (4.54)**	**3.6 (4.49)**

[1] No data collected for this time point

No statistical analysis provided for Cumulative Number of Gadolinium-enhancing T1 Lesions From the Last Natalizumab Infusion

7. Secondary: Number of Participants With Adverse Events (AE), Serious Adverse Events (SAE) and Death During Washout Period [Time Frame: Baseline to maximum of 16 weeks]

Measure Type	Secondary
Measure Title	Number of Participants With Adverse Events (AE), Serious Adverse Events (SAE) and Death During Washout Period
Measure Description	Adverse events were summarized by the number of patients having any adverse event overall.
Time Frame	Baseline to maximum of 16 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.
The Safety Set included all randomized patients, analyzed according to the washout group most closely corresponding to the day on which they first received fingolimod

Reporting Groups

	Description
8-week Washout + Fingolimod (FTY720)	8-week washout (8 weeks no treatment) followed by 24 weeks of treatment with fingolimod 0.5mg once a day
12-week Washout + Fingolimod (FTY720)	12-week washout (8 weeks no treatment and 4 weeks placebo) followed by 20 weeks of treatment

	with fingolimod 0.5mg once a day
16-week Washout + Fingolimod (FTY720)	16-week washout (8 weeks no treatment and 8 weeks placebo) followed by 16 weeks of treatment with fingolimod 0.5mg once a day

Measured Values

	8-week Washout + Fingolimod (FTY720)	12-week Washout + Fingolimod (FTY720)	16-week Washout + Fingolimod (FTY720)
Number of Participants Analyzed [units: participants]	**50**	**42**	**50**
Number of Participants With Adverse Events (AE), Serious Adverse Events (SAE) and Death During Washout Period [units: participants]			
Any Adverse Events	**13**	**12**	**25**
Serious Adverse Events	**0**	**0**	**1**
Death	**0**	**0**	**0**

No statistical analysis provided for Number of Participants With Adverse Events (AE), Serious Adverse Events (SAE) and Death During Washout Period

8. Secondary: Number of Participants With Adverse Events (AE), Serious Adverse Events (SAE) and Death During Fingolimod Treatment [Time Frame: Baseline to maximum of 16 weeks]

Measure Type	Secondary
Measure Title	Number of Participants With Adverse Events (AE), Serious Adverse Events (SAE) and Death During Fingolimod Treatment
Measure Description	Adverse events were summarized by the number of patients having any adverse event overall.
Time Frame	Baseline to maximum of 16 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.
The Safety Set included all randomized patients, analyzed according to the washout group most closely corresponding to the day on which they first received fingolimod

Reporting Groups

	Description
8-week Washout + Fingolimod (FTY720)	8-week washout (8 weeks no treatment) followed by 24 weeks of treatment with fingolimod 0.5mg once a day
12-week Washout + Fingolimod (FTY720)	12-week washout (8 weeks no treatment and 4 weeks placebo) followed by 20 weeks of treatment with fingolimod 0.5mg once a day
16-week Washout + Fingolimod (FTY720)	16-week washout (8 weeks no treatment and 8 weeks placebo) followed by 16 weeks of treatment with fingolimod 0.5mg once a day

Measured Values

	8-week Washout + Fingolimod (FTY720)	**12-week Washout + Fingolimod (FTY720)**	**16-week Washout + Fingolimod (FTY720)**
Number of Participants Analyzed [units: participants]	**50**	**42**	**50**
Number of Participants With Adverse Events (AE), Serious Adverse Events (SAE) and Death During Fingolimod Treatment [units: participants]			
Any Adverse Events	**35**	**20**	**28**
Serious Adverse Events	**2**	**5**	**3**
Death	**0**	**0**	**0**

No statistical analysis provided for Number of Participants With Adverse Events (AE), Serious Adverse Events (SAE) and Death During Fingolimod Treatment

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	Safety Set (SS): The Safety Set included all randomized patients, analyzed according to the washout group most closely corresponding to the day on which they first received fingolimod. Safety and tolerability analysis were performed on the SS unless otherwise specified.

Reporting Groups

	Description
8-week Washout + Fingolimod (FTY720)	8-week washout (8 weeks no treatment) followed by 24 weeks of treatment with fingolimod 0.5mg once a day
12-week Washout + Fingolimod (FTY720)	12-week washout (8 weeks no treatment and 4 weeks placebo) followed by 20 weeks of treatment with fingolimod 0.5mg once a day
16-week Washout + Fingolimod (FTY720)	16-week washout (8 weeks no treatment and 8 weeks placebo) followed by 16 weeks of treatment with fingolimod 0.5mg once a day

Serious Adverse Events

	8-week Washout + Fingolimod (FTY720)	12-week Washout + Fingolimod (FTY720)	16-week Washout + Fingolimod (FTY720)
Total, serious adverse events			
# participants affected / at risk	**2/50 (4.00%)**	**5/42 (11.90%)**	**4/50 (8.00%)**
Cardiac disorders			

Bradycardia † [1]			
# participants affected / at risk	**0/50 (0.00%)**	**0/42 (0.00%)**	**1/50 (2.00%)**
Hepatobiliary disorders			
Cholecystitis acute † [1]			
# participants affected / at risk	**0/50 (0.00%)**	**1/42 (2.38%)**	**0/50 (0.00%)**
Cholelithiasis † [1]			
# participants affected / at risk	**0/50 (0.00%)**	**1/42 (2.38%)**	**0/50 (0.00%)**
Infections and infestations			
Pharyngitis † [1]			
# participants affected / at risk	**0/50 (0.00%)**	**1/42 (2.38%)**	**0/50 (0.00%)**
Pneumonia † [1]			
# participants affected / at risk	**1/50 (2.00%)**	**0/42 (0.00%)**	**0/50 (0.00%)**
Injury, poisoning and procedural complications			
Femur fracture † [1]			
# participants affected / at risk	**1/50 (2.00%)**	**0/42 (0.00%)**	**0/50 (0.00%)**
Investigations			
Electrocardiogram T wave inversion † [1]			
# participants affected / at risk	**0/50 (0.00%)**	**0/42 (0.00%)**	**1/50 (2.00%)**
Heart rate decreased † [1]			
# participants affected / at risk	**0/50 (0.00%)**	**1/42 (2.38%)**	**0/50 (0.00%)**
Nervous system disorders			
Epilepsy † [1]			
# participants affected / at risk	**0/50 (0.00%)**	**1/42 (2.38%)**	**0/50 (0.00%)**

Multiple sclerosis relapse † 1			
# participants affected / at risk	**0/50 (0.00%)**	**0/42 (0.00%)**	**2/50 (4.00%)**
Syncope † 1			
# participants affected / at risk	**0/50 (0.00%)**	**1/42 (2.38%)**	**0/50 (0.00%)**
Psychiatric disorders			
Depression suicidal † 1			
# participants affected / at risk	**0/50 (0.00%)**	**1/42 (2.38%)**	**0/50 (0.00%)**
Major depression † 1			
# participants affected / at risk	**0/50 (0.00%)**	**0/42 (0.00%)**	**1/50 (2.00%)**
Mental disorder due to a general medical condition † 1			
# participants affected / at risk	**0/50 (0.00%)**	**0/42 (0.00%)**	**1/50 (2.00%)**
Personality change † 1			
# participants affected / at risk	**0/50 (0.00%)**	**0/42 (0.00%)**	**1/50 (2.00%)**

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

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	Safety Set (SS): The Safety Set included all randomized patients, analyzed according to the washout group most closely corresponding to the day on which they first received fingolimod. Safety and tolerability analysis were performed on the SS unless otherwise specified.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
8-week Washout + Fingolimod (FTY720)	8-week washout (8 weeks no treatment) followed by 24 weeks of treatment with fingolimod 0.5mg once a day
12-week Washout + Fingolimod (FTY720)	12-week washout (8 weeks no treatment and 4 weeks placebo) followed by 20 weeks of treatment with fingolimod 0.5mg once a day
16-week Washout + Fingolimod (FTY720)	16-week washout (8 weeks no treatment and 8 weeks placebo) followed by 16 weeks of treatment with fingolimod 0.5mg once a day

Other Adverse Events

	8-week Washout + Fingolimod (FTY720)	12-week Washout + Fingolimod (FTY720)	16-week Washout + Fingolimod (FTY720)
Total, other (not including serious) adverse events			
# participants affected / at risk	**17/50 (34.00%)**	**7/42 (16.67%)**	**14/50 (28.00%)**
Infections and infestations			
Nasopharyngitis † [1]			
# participants affected / at risk	**7/50 (14.00%)**	**1/42 (2.38%)**	**2/50 (4.00%)**
Oral herpes † [1]			
# participants affected / at risk	**1/50 (2.00%)**	**3/42 (7.14%)**	**1/50 (2.00%)**
Sinusitis † [1]			
# participants affected / at risk	**2/50 (4.00%)**	**1/42 (2.38%)**	**3/50 (6.00%)**
Urinary tract infection † [1]			
# participants affected / at risk	**3/50 (6.00%)**	**1/42 (2.38%)**	**0/50 (0.00%)**
Musculoskeletal and connective tissue			

disorders			
Myalgia † 1			
# participants affected / at risk	**3/50 (6.00%)**	**0/42 (0.00%)**	**0/50 (0.00%)**
Nervous system disorders			
Dizziness † 1			
# participants affected / at risk	**3/50 (6.00%)**	**1/42 (2.38%)**	**3/50 (6.00%)**
Headache † 1			
# participants affected / at risk	**5/50 (10.00%)**	**3/42 (7.14%)**	**10/50 (20.00%)**
Psychiatric disorders			
Depression † 1			
# participants affected / at risk	**1/50 (2.00%)**	**1/42 (2.38%)**	**3/50 (6.00%)**
Respiratory, thoracic and mediastinal disorders			
Cough † 1			
# participants affected / at risk	**3/50 (6.00%)**	**0/42 (0.00%)**	**1/50 (2.00%)**
Oropharyngeal pain † 1			
# participants affected / at risk	**4/50 (8.00%)**	**0/42 (0.00%)**	**0/50 (0.00%)**

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

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

Study was terminated due to new data on nataluzimab washout prior to treatment with other disease modifying treatments. The power to detect statistically significant differences between the washout groups based on the (-)binomial is estimated 30-40%.

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 terms and conditions of Novartis' agreements with its investigators may vary. However, Novartis does not prohibit any investigator from publishing. Any publications from a single-site are postponed until the publication of pooled data (i.e.,data from all sites) in clinical trial or disclosure of trial results in their entirety.

Results Point of Contact:

Name/Title: Study Director
Organization: Novartis Pharnaceuticals
phone: 862-778-8300

No publications provided

Responsible Party:	Novartis (Novartis Pharmaceuticals)
ClinicalTrials.gov Identifier:	NCT01499667 History of Changes
Other Study ID Numbers:	**CFTY720D2324** 2011-001442-15 (EudraCT Number)
Study First Received:	August 18, 2011
Results First Received:	November 25, 2013
Last Updated:	August 6, 2014
Health Authority:	United States: Food and Drug Administration Germany: Federal Institute for Drugs and Medical Devices United Kingdom: Medicines and Healthcare Products Regulatory Agency European Union: European Medicines Agency