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Trial record **1 of 1** for: CFTY720D2320

Previous Study | Return to List | Next Study

# Effect of Treatment With Fingolimod on the Immune Response Following Seasonal Flu Vaccination and Tetanus Booster Injection in Patients With Relapsing Multiple Sclerosis (MS)

**This study has been completed.**

**Sponsor:**
Novartis

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

**ClinicalTrials.gov Identifier:**
NCT01199861

First received: September 9, 2010
Last updated: May 15, 2012
Last verified: May 2012
History of Changes

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

Results First Received: May 15, 2012

| | |
|---|---|
| **Study Type:** | Interventional |
| **Study Design:** | Allocation: Randomized; Intervention Model: Parallel Assignment;<br>Masking: Double Blind (Subject, Investigator, Outcomes Assessor);<br>Primary Purpose: Treatment |
| **Condition:** | Relapsing Multiple Sclerosis |
| **Interventions:** | Drug: Fingolimod<br>Drug: Placebo<br>Biological: Seasonal influenza vaccine |

| | |
|---|---|
| | Biological: Tetanus toxoid vaccine |

## 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 |
|---|
| Participants were randomized in a 2:1 ratio to fingolimod 0.5 mg once daily or matching placebo. |

### Reporting Groups

| | Description |
|---|---|
| **Fingolimod** | Participants received Fingolimod 0.5 mg capsules orally once daily for 12 weeks. At Week 6 of study treatment participants received a seasonal influenza vaccination and a tetanus booster vaccination. |
| **Placebo** | Participants received placebo tablets orally once daily for 12 weeks. At Week 6 of study treatment participants received a seasonal influenza vaccination and a tetanus booster vaccination. |

### Participant Flow: Overall Study

| | Fingolimod | Placebo |
|---|---|---|
| **STARTED** | **95** | **43** |
| **COMPLETED** | **93** | **43** |
| **NOT COMPLETED** | **2** | **0** |
| **Administrative problems** | **1** | **0** |
| **Adverse Event** | **1** | **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** |
|---|---|
| **Fingolimod** | Participants received Fingolimod 0.5 mg capsules orally once daily for 12 weeks. At Week 6 of study treatment participants received a seasonal influenza vaccination and a tetanus booster vaccination. |
| **Placebo** | Participants received placebo tablets orally once daily for 12 weeks. At Week 6 of study treatment participants received a seasonal influenza vaccination and a tetanus booster vaccination. |
| **Total** | Total of all reporting groups |

### Baseline Measures

| | **Fingolimod** | **Placebo** | **Total** |
|---|---|---|---|
| **Number of Participants [units: participants]** | **95** | **43** | **138** |
| **Age [units: years] Mean (Standard Deviation)** | **37.4 (8.37)** | **39.2 (8.67)** | **37.9 (8.48)** |
| **Age, Customized [units: participants]** | | | |
| **18-30** | **25** | **8** | **33** |

| | | | |
|---|---|---|---|
| **31-40** | **35** | **14** | **49** |
| **41-55** | **35** | **21** | **56** |
| **Gender [units: participants]** | | | |
| **Female** | **65** | **29** | **94** |
| **Male** | **30** | **14** | **44** |

## Outcome Measures

Hide All Outcome Measures

1. Primary: Immune Response 3 Weeks After Seasonal Influenza Vaccination [ Time Frame: Week 6 (pre-vaccination) and 3 weeks after vaccination (Study week 9) ]

| | |
|---|---|
| **Measure Type** | Primary |
| **Measure Title** | Immune Response 3 Weeks After Seasonal Influenza Vaccination |
| **Measure Description** | Percentage of participants who responded to treatment with the seasonal influenza vaccine 3 weeks after vaccination. Response was defined as patients fulfilling one of the following criteria for at least one of the three strains contained in the seasonal influenza vaccine:<br>• Seroconversion: The pre-vaccination antibody titer measurement was <1:10 and the post-vaccination measurement is ≥1:40.<br>• Significant increase in antibody titer: The pre-vaccination antibody titer measurement was ≥1:10 and the increase in antibody titer from this to the post-vaccination measurement is ≥ 4-fold. |
| **Time Frame** | Week 6 (pre-vaccination) and 3 weeks after vaccination (Study week 9) |
| **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 full analysis set which includes all patients who were randomized and received at least 1 dose of study drug, and for whom data were available. |

**Reporting Groups**

| | Description |
|---|---|
| **Fingolimod** | Participants received Fingolimod 0.5 mg capsules orally once daily for 12 weeks. At Week 6 of study treatment participants received a seasonal influenza vaccination and a tetanus booster vaccination. |
| **Placebo** | Participants received placebo tablets orally once daily for 12 weeks. At Week 6 of study treatment participants received a seasonal influenza vaccination and a tetanus booster vaccination. |

**Measured Values**

| | Fingolimod | Placebo |
|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **90** | **43** |
| **Immune Response 3 Weeks After Seasonal Influenza Vaccination [units: percentage of participants]** | **53.3** | **83.7** |

**No statistical analysis provided for Immune Response 3 Weeks After Seasonal Influenza Vaccination**

2. Secondary: Immune Response 6 Weeks After Seasonal Influenza Vaccination [ Time Frame: Week 6 (pre-vaccination) and 6 weeks after vaccination (Study week 12). ]

| | |
|---|---|
| **Measure Type** | Secondary |
| **Measure Title** | Immune Response 6 Weeks After Seasonal Influenza Vaccination |
| **Measure Description** | Percentage of participants who responded to treatment with the seasonal influenza vaccine 6 weeks after vaccination. Response was defined as patients fulfilling one of the following criteria for at least one of the three strains contained in the seasonal influenza vaccine: |

| | |
|---|---|
| | • Seroconversion: The pre-vaccination antibody titer measurement was <1:10 and the post-vaccination measurement is ≥1:40.<br>• Significant increase in antibody titer: The pre-vaccination antibody titer measurement was ≥1:10 and the increase in antibody titer from this to the post-vaccination measurement is ≥ 4-fold. |
| **Time Frame** | Week 6 (pre-vaccination) and 6 weeks after vaccination (Study week 12). |
| **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.** |
|---|
| Full analysis set for whom data were available. |

**Reporting Groups**

| | **Description** |
|---|---|
| **Fingolimod** | Participants received Fingolimod 0.5 mg capsules orally once daily for 12 weeks. At Week 6 of study treatment participants received a seasonal influenza vaccination and a tetanus booster vaccination. |
| **Placebo** | Participants received placebo tablets orally once daily for 12 weeks. At Week 6 of study treatment participants received a seasonal influenza vaccination and a tetanus booster vaccination. |

**Measured Values**

| | **Fingolimod** | **Placebo** |
|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **88** | **43** |
| **Immune Response 6 Weeks After Seasonal Influenza Vaccination [units: percentage of participants]** | **43.2** | **74.4** |

**No statistical analysis provided for Immune Response 6 Weeks After Seasonal Influenza Vaccination**

3. Secondary: Immune Response 3 Weeks After Tetanus Toxoid Booster [ Time Frame: Week 6 (pre-vaccination) and 3 weeks after vaccination (Study Week 9) ]

| | |
|---|---|
| **Measure Type** | Secondary |
| **Measure Title** | Immune Response 3 Weeks After Tetanus Toxoid Booster |
| **Measure Description** | Percentage of participants with an immune response to a single dose of tetanus toxoid three weeks after vaccination. A patient was considered a responder to tetanus toxoid booster vaccination if one of the following criteria was met:<br>1. Seroconversion: The pre-vaccination antibody titer measurement was <0.1 IU/ml and the post-vaccination measurement was ≥0.4 IU/ml.<br>2. Significant increase: The pre-vaccination antibody titer measurement was ≥0.1 IU/ml and the increase in antibody titer from this to the post-vaccination measurement was ≥4- fold. |
| **Time Frame** | Week 6 (pre-vaccination) and 3 weeks after vaccination (Study Week 9) |
| **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.** |
|---|
| Full analysis set for whom data were available. |

**Reporting Groups**

| | **Description** |
|---|---|
| **Fingolimod** | Participants received Fingolimod 0.5 mg capsules orally once daily for 12 weeks. At Week 6 of study treatment participants received a seasonal influenza vaccination and a tetanus booster vaccination. |
| **Placebo** | Participants received placebo tablets orally once daily for 12 weeks. At Week 6 of study treatment participants received a seasonal influenza vaccination and a tetanus booster vaccination. |

**Measured Values**

| | Fingolimod | Placebo |
|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **90** | **43** |
| **Immune Response 3 Weeks After Tetanus Toxoid Booster [units: percentage of participants]** | **40.0** | **60.5** |

**No statistical analysis provided for Immune Response 3 Weeks After Tetanus Toxoid Booster**

4. Secondary: Immune Response 6 Weeks After Tetanus Toxoid Booster [ Time Frame: Week 6 (pre-vaccination) and 6 weeks after vaccination (Study Week 12) ]

| | |
|---|---|
| **Measure Type** | Secondary |
| **Measure Title** | Immune Response 6 Weeks After Tetanus Toxoid Booster |
| **Measure Description** | Percentage of participants with an immune response to a single dose of tetanus toxoid six weeks after vaccination. A patient was considered a responder to tetanus toxoid booster vaccination if one of the following criteria was met:<br>1. Seroconversion: The pre-vaccination antibody titer measurement was <0.1 IU/ml and the post-vaccination measurement was ≥0.4 IU/ml.<br>2. Significant increase: The pre-vaccination antibody titer measurement was ≥0.1 IU/ml and the increase in antibody titer from this to the post-vaccination measurement was ≥4- fold. |
| **Time Frame** | Week 6 (pre-vaccination) and 6 weeks after vaccination (Study Week 12) |
| **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.** |
|---|
| Full analysis set for whom data were available. |

**Reporting Groups**

| | Description |
|---|---|
| **Fingolimod** | Participants received Fingolimod 0.5 mg capsules orally once daily for 12 weeks. At Week 6 of study treatment participants received a seasonal influenza vaccination and a tetanus booster vaccination. |
| **Placebo** | Participants received placebo tablets orally once daily for 12 weeks. At Week 6 of study treatment participants received a seasonal influenza vaccination and a tetanus booster vaccination. |

**Measured Values**

| | Fingolimod | Placebo |
|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **88** | **43** |
| **Immune Response 6 Weeks After Tetanus Toxoid Booster [units: percentage of participants]** | **37.5** | **48.8** |

**No statistical analysis provided for Immune Response 6 Weeks After Tetanus Toxoid Booster**

5. Secondary: Change From Baseline in Seasonal Influenza Vaccine Antibody-titer 3 Weeks After Vaccination [ Time Frame: Pre-vaccination (Week 6) and 3 weeks after vaccination (Study Week 9). ]

| | |
|---|---|
| **Measure Type** | Secondary |
| **Measure Title** | Change From Baseline in Seasonal Influenza Vaccine Antibody-titer 3 Weeks After Vaccination |
| **Measure Description** | Change from Baseline was expressed by the ratio of post-vaccination to pre-vaccination antibody titer for each of the three strains included in the seasonal influenza vaccine. Inhibition of an immune response to each strain included in the seasonal influenza vaccine was assessed by the relative difference of the geometric mean antibody titer ratio on fingolimod as compared to placebo three weeks after a single dose of seasonal influenza vaccine. |
| **Time Frame** | Pre-vaccination (Week 6) and 3 weeks after vaccination (Study Week 9). |
| **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.** |
|---|
| Full analysis set for whom data were available. |

**Reporting Groups**

| | **Description** |
|---|---|
| **Fingolimod** | Participants received Fingolimod 0.5 mg capsules orally once daily for 12 weeks. At Week 6 of study treatment participants received a seasonal influenza vaccination and a tetanus booster vaccination. |
| **Placebo** | Participants received placebo tablets orally once daily for 12 weeks. At Week 6 of study treatment participants received a seasonal influenza vaccination and a tetanus booster vaccination. |

**Measured Values**

| | **Fingolimod** | **Placebo** |
|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **90** | **43** |
| **Change From Baseline in Seasonal Influenza Vaccine Antibody-titer 3 Weeks After Vaccination [units: ratio]** | | |
| **A/California/7/09(H1N1)** | **2.45** | **4.14** |
| **A/Perth/16/2009(H3N2)** | **0.49** | **0.36** |
| **B/Brisbane/60/2008** | **1.34** | **2.40** |

**Statistical Analysis 1 for Change From Baseline in Seasonal Influenza Vaccine Antibody-titer 3 Weeks After Vaccination**

| | |
|---|---|
| **Groups** [1] | All groups |
| **Percent Inhibition** [2] | 41.0 |

| | |
|---|---|
| [1] | Additional details about the analysis, such as null hypothesis and power calculation: |
| | The inhibition of an immune response to the A/California/7/09 (H1N1) strain of the seasonal influenza vaccine was assessed by the relative difference of the geometric mean antibody titer ratio on fingolimod as compared to placebo three weeks after a single dose of seasonal influenza vaccine. |
| [2] | Other relevant estimation information: |
| | One minus the back-transformed estimate for the treatment difference was interpreted as the relative inhibition of an immune response caused by fingolimod 0.5 mg compared to placebo; it was presented as a percentage and referred to as ‘inhibition'. |

**Statistical Analysis 2 for Change From Baseline in Seasonal Influenza Vaccine Antibody-titer 3 Weeks After Vaccination**

| | |
|---|---|
| **Groups** [1] | All groups |
| **Percent Inhibition** [2] | -35.0 |

| | |
|---|---|
| [1] | Additional details about the analysis, such as null hypothesis and power calculation: |
| | The inhibition of an immune response to the A/Perth/16/2009 (H3N2) strain of the seasonal influenza vaccine was assessed by the relative difference of the geometric mean antibody titer ratio on fingolimod as compared to placebo three weeks after a single dose of seasonal influenza vaccine. |
| [2] | Other relevant estimation information: |
| | One minus the back-transformed estimate for the treatment difference was interpreted as the relative inhibition of an immune response caused by fingolimod 0.5 mg compared to placebo; it was presented as a percentage and referred to as 'inhibition'. |

**Statistical Analysis 3 for Change From Baseline in Seasonal Influenza Vaccine Antibody-titer 3 Weeks After Vaccination**

| | |
|---|---|
| **Groups** [1] | All groups |
| **Percent Inhibition** [2] | 44.0 |

| | |
|---|---|
| [1] | Additional details about the analysis, such as null hypothesis and power calculation: |
| | The inhibition of an immune response to the B/Brisbane/60/2008 strain of the seasonal influenza vaccine was assessed by the relative difference of the geometric mean antibody titer ratio on fingolimod as compared to placebo three weeks after a single dose of seasonal influenza vaccine. |

| | |
|---|---|
| [2] | Other relevant estimation information: |
| | One minus the back-transformed estimate for the treatment difference was interpreted as the relative inhibition of an immune response caused by fingolimod 0.5 mg compared to placebo; it was presented as a percentage and referred to as 'inhibition'. |

6. Secondary: Change From Baseline in Seasonal Influenza Vaccine Antibody-titer 6 Weeks After Vaccination [ Time Frame: Pre-vaccination (Week 6) and 6 weeks after vaccination (Study Week 12). ]

| | |
|---|---|
| **Measure Type** | Secondary |
| **Measure Title** | Change From Baseline in Seasonal Influenza Vaccine Antibody-titer 6 Weeks After Vaccination |
| **Measure Description** | Change from Baseline was expressed by the ratio of post-vaccination to pre-vaccination antibody titer for each of the three strains included in the seasonal influenza vaccine. Inhibition of an immune response to each strain included in the seasonal influenza vaccine was assessed by the relative difference of the geometric mean antibody titer ratio on fingolimod as compared to placebo six weeks after a single dose of seasonal influenza vaccine. |
| **Time Frame** | Pre-vaccination (Week 6) and 6 weeks after vaccination (Study Week 12). |
| **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.** |
|---|
| Full analysis set for whom data were available. |

**Reporting Groups**

| | **Description** |
|---|---|
| **Fingolimod** | Participants received Fingolimod 0.5 mg capsules orally once daily for 12 weeks. At Week 6 of study treatment participants received a seasonal influenza vaccination and a tetanus booster vaccination. |
| **Placebo** | Participants received placebo tablets orally once daily for 12 weeks. At Week 6 of study treatment participants received a seasonal influenza vaccination and a tetanus booster vaccination. |

**Measured Values**

| | Fingolimod | Placebo |
|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **88** | **43** |
| **Change From Baseline in Seasonal Influenza Vaccine Antibody-titer 6 Weeks After Vaccination [units: ratio]** | | |
| **A/California/7/09(H1N1)** | **1.81** | **2.91** |
| **A/Perth/16/2009(H3N2)** | **0.36** | **0.28** |
| **B/Brisbane/60/2008** | **1.08** | **2.07** |

**Statistical Analysis 1 for Change From Baseline in Seasonal Influenza Vaccine Antibody-titer 6 Weeks After Vaccination**

| | |
|---|---|
| **Groups** [1] | All groups |
| **Percent Inhibition** [2] | 38.0 |

| | |
|---|---|
| [1] | Additional details about the analysis, such as null hypothesis and power calculation: |
| | The inhibition of an immune response to the A/California/7/09 (H1N1) strain of the seasonal influenza vaccine was assessed by the relative difference of the geometric mean antibody titer ratio on fingolimod as compared to placebo six weeks after a single dose of seasonal influenza vaccine. |
| [2] | Other relevant estimation information: |
| | One minus the back-transformed estimate for the treatment difference was interpreted as the relative inhibition of an immune response caused by fingolimod 0.5 mg compared to placebo; it was presented as a percentage and referred to as 'inhibition'. |

**Statistical Analysis 2 for Change From Baseline in Seasonal Influenza Vaccine Antibody-titer 6 Weeks After Vaccination**

| | |
|---|---|
| **Groups** [1] | All groups |
| **Percent Inhibition** [2] | -28.0 |

| | |
|---|---|
| [1] | Additional details about the analysis, such as null hypothesis and power calculation: |
| | The inhibition of an immune response to the A/Perth/16/2009 (H3N2) strain of the seasonal influenza vaccine was assessed by the relative difference of the geometric mean antibody titer ratio on fingolimod as compared to placebo six weeks after a single dose of seasonal influenza vaccine. |
| [2] | Other relevant estimation information: |
| | One minus the back-transformed estimate for the treatment difference was interpreted as the relative inhibition of an immune response caused by fingolimod 0.5 mg compared to placebo; it was presented as a percentage and referred to as 'inhibition'. |

**Statistical Analysis 3 for Change From Baseline in Seasonal Influenza Vaccine Antibody-titer 6 Weeks After Vaccination**

| | |
|---|---|
| **Groups** [1] | All groups |
| **Percent Inhibition** [2] | 48.0 |

| | |
|---|---|
| [1] | Additional details about the analysis, such as null hypothesis and power calculation: |
| | The inhibition of an immune response to the B/Brisbane/60/2008 strain of the seasonal influenza vaccine was assessed by the relative difference of the geometric mean antibody titer ratio on fingolimod as compared to placebo six weeks after a single dose of seasonal influenza vaccine. |
| [2] | Other relevant estimation information: |
| | One minus the back-transformed estimate for the treatment difference was interpreted as the relative inhibition of an immune response caused by fingolimod 0.5 mg compared to placebo; it was presented as a percentage and referred to as 'inhibition'. |

7. Secondary: Number of Participants With Adverse Events (AEs) [ Time Frame: From first dose of study drug until 45 days after the last dose of study drug (130 days). ]

| | |
|---|---|
| **Measure Type** | Secondary |
| **Measure Title** | Number of Participants With Adverse Events (AEs) |
| **Measure Description** | Relationship to study drug was determined by the investigator (suspected/not suspected). |

| | |
|---|---|
| | A serious AE is defined as an event which fulfills one of the following criteria:<br>• is fatal or life-threatening;<br>• results in persistent or significant disability/incapacity;<br>• constitutes a congenital anomaly/birth defect;<br>• requires inpatient hospitalization or prolongation of existing hospitalization;<br>• is medically significant, i.e., jeopardizes the patient or may require intervention to prevent one of the outcomes listed above. |
| **Time Frame** | From first dose of study drug until 45 days after the last dose of study drug (130 days). |
| **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.** |
|---|
| Safety set - all patients who received at least 1 dose of study drug. |

**Reporting Groups**

| | **Description** |
|---|---|
| **Fingolimod** | Participants received Fingolimod 0.5 mg capsules orally once daily for 12 weeks. At Week 6 of study treatment participants received a seasonal influenza vaccination and a tetanus booster vaccination. |
| **Placebo** | Participants received placebo tablets orally once daily for 12 weeks. At Week 6 of study treatment participants received a seasonal influenza vaccination and a tetanus booster vaccination. |

**Measured Values**

| | **Fingolimod** | **Placebo** |
|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **95** | **43** |
| **Number of Participants With Adverse Events (AEs) [units: participants]** | | |

| | | |
|---|---|---|
| **Any adverse event** | **82** | **34** |
| **AE related to study drug** | **42** | **11** |
| **Serious adverse event** | **1** | **2** |
| **Adverse events leading to discontinuation** | **1** | **0** |

**No statistical analysis provided for Number of Participants With Adverse Events (AEs)**

## Serious Adverse Events

Hide Serious Adverse Events

| | |
|---|---|
| **Time Frame** | No text entered. |
| **Additional Description** | No text entered. |

### Reporting Groups

| | Description |
|---|---|
| **Fingolimod** | Participants received Fingolimod 0.5 mg capsules orally once daily for 12 weeks. At Week 6 of study treatment participants received a seasonal influenza vaccination and a tetanus booster vaccination. |
| **Placebo** | Participants received placebo tablets orally once daily for 12 weeks. At Week 6 of study treatment participants received a seasonal influenza vaccination and a tetanus booster vaccination. |

### Serious Adverse Events

| | Fingolimod | Placebo |
|---|---|---|
| **Total, serious adverse events** | | |
| **# participants affected / at risk** | **1/95 (1.05%)** | **2/43 (4.65%)** |
| **Infections and infestations** | | |
| | | |

| | | |
|---|---|---|
| **Herpes zoster † 1** | | |
| **# participants affected / at risk** | **0/95 (0.00%)** | **1/43 (2.33%)** |
| **Injury, poisoning and procedural complications** | | |
| **Hip fracture † 1** | | |
| **# participants affected / at risk** | **0/95 (0.00%)** | **1/43 (2.33%)** |
| **Nervous system disorders** | | |
| **Paraparesis † 1** | | |
| **# participants affected / at risk** | **1/95 (1.05%)** | **0/43 (0.00%)** |

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 14.0

## 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 |
|---|---|
| **Fingolimod** | Participants received Fingolimod 0.5 mg capsules orally once daily for 12 weeks. At Week 6 of study treatment participants received a seasonal influenza vaccination and a tetanus booster vaccination. |
| **Placebo** | Participants received placebo tablets orally once daily for 12 weeks. At Week 6 of study treatment participants received a seasonal influenza vaccination and a tetanus booster vaccination. |

## Other Adverse Events

| | Fingolimod | Placebo |
|---|---|---|
| Total, other (not including serious) adverse events | | |
| # participants affected / at risk | 51/95 (53.68%) | 22/43 (51.16%) |
| Blood and lymphatic system disorders | | |
| Lymphopenia † 1 | | |
| # participants affected / at risk | 10/95 (10.53%) | 0/43 (0.00%) |
| Gastrointestinal disorders | | |
| Diarrhoea † 1 | | |
| # participants affected / at risk | 3/95 (3.16%) | 3/43 (6.98%) |
| Nausea † 1 | | |
| # participants affected / at risk | 2/95 (2.11%) | 4/43 (9.30%) |
| General disorders | | |
| Fatigue † 1 | | |
| # participants affected / at risk | 3/95 (3.16%) | 3/43 (6.98%) |
| Infections and infestations | | |
| Nasopharyngitis † 1 | | |
| # participants affected / at risk | 15/95 (15.79%) | 8/43 (18.60%) |
| Upper respiratory tract infection † 1 | | |
| # participants affected / at risk | 11/95 (11.58%) | 6/43 (13.95%) |
| Urinary tract infection † 1 | | |
| # participants affected / at risk | 5/95 (5.26%) | 2/43 (4.65%) |
| Nervous system disorders | | |
| | | |

| | | |
|---|---|---|
| **Headache † 1** | | |
| **# participants affected / at risk** | **18/95 (18.95%)** | **4/43 (9.30%)** |
| **Respiratory, thoracic and mediastinal disorders** | | |
| **Cough † 1** | | |
| **# participants affected / at risk** | **7/95 (7.37%)** | **0/43 (0.00%)** |

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 14.0

## 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:<br>☐ 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 the pooled data (i.e., data from all sites) in the clinical trial.

**Results Point of Contact:**

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

**No publications provided**

| | |
|---|---|
| Responsible Party: | Novartis |
| ClinicalTrials.gov Identifier: | NCT01199861 History of Changes |
| Other Study ID Numbers: | **CFTY720D2320**<br>2010-019028-30 ( EudraCT Number ) |
| Study First Received: | September 9, 2010 |
| Results First Received: | May 15, 2012 |
| Last Updated: | May 15, 2012 |
| Health Authority: | Belgium: Federal Agency for Medicinal Products and Health Products<br>Canada: Health Canada<br>Finland: Finnish Medicines Agency<br>FRANCE: agence francaise de sécurité sanitaire des produits des santé<br>GUATEMALA: Departamento de Regulación, y Control de Productos Farmacéuticos y Afines<br>Poland: Office for Registration of Medicinal Products, Medical Devices and Biocidal Products<br>Spain: Agencia Española de Medicamentos y Productos Sanitarios<br>Switzerland: Swissmedic<br>United Kingdom: Medicines and Healthcare Products Regulatory Agency |