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Trial record **1 of 1** for: CSFO327N2302

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# Efficacy Safety, and Tolerability of Topical Terbinafine in Patients With Mild to Moderate Toenail Fungus of the Big Toenail

**This study has been completed.**

**Sponsor:**
Novartis Pharmaceuticals

**Information provided by:**
Novartis

**ClinicalTrials.gov Identifier:**
NCT00443820

First received: March 2, 2007
Last updated: March 22, 2011
Last verified: March 2011
History of Changes

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

Results First Received: January 19, 2011

| | |
|---|---|
| **Study Type:** | Interventional |
| **Study Design:** | Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study;<br>Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator);<br>Primary Purpose: Treatment |
| **Condition:** | Onychomycosis |
| **Interventions:** | Drug: terbinafine<br>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 |
|---|
| This randomized, double -blind, vehicle -controlled, multicenter, parallel group study was designed to assess the efficacy, safety and tolerability of a topical formulation of terbinafine hydrogen chloride 10% topical solution (TTS10%) applied daily in patients with toenail onychomycosis. Started 07 DEC 2006 and ending 27 JUN 2008. |

### 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 |
|---|---|
| **Terbinafine 24 Weeks** | Terbinafine hydrochloride (HCl) 10 % Nail Solution for Onychomycosis (NSO) for 24 weeks |
| **Vehicle 24 Weeks** | Vehicle (placebo) for 24 weeks |
| **Terbinafine 48 Weeks** | Terbinafine hydrochloride (HCl) 10 % Nail Solution for Onychomycosis (NSO) for 48 weeks |
| **Vehicle 48 Weeks** | Vehicle (placebo) for 48 weeks |

**Participant Flow: Overall Study**

| | Terbinafine 24 Weeks | Vehicle 24 Weeks | Terbinafine 48 Weeks | Vehicle 48 Weeks |
|---|---|---|---|---|
| STARTED | 133 | 130 | 135 | 128 |
| Safety Population | 131 [1] | 129 | 134 | 126 |
| COMPLETED | 112 | 111 [2] | 117 | 111 |
| NOT COMPLETED | 21 | 19 | 18 | 17 |
| Adverse Event | 1 | 1 | 0 | 0 |
| Lack of Efficacy | 3 | 2 | 1 | 1 |
| Protocol Violation | 2 | 1 | 2 | 1 |
| Withdrawal by Subject | 6 | 7 | 8 | 9 |
| Lost to Follow-up | 9 | 8 | 6 | 5 |
| Administrative problems | 0 | 0 | 0 | 1 |
| Death | 0 | 0 | 1 | 0 |

[1] Participants who received study drug and had at least one post-baseline safety assessment.
[2] A participant from this gr. discont'ed due to renal failure, was counted as an AE and also as a SAE.

## 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 |
|---|---|
| Terbinafine 24 Weeks | Terbinafine hydrochloride (HCl) 10 % Nail Solution for Onychomycosis (NSO) for 24 weeks |
| Vehicle 24 Weeks | Vehicle (placebo) for 24 weeks |
| Terbinafine 48 Weeks | Terbinafine hydrochloride (HCl) 10 % Nail Solution for Onychomycosis (NSO) for 48 weeks |
| Vehicle 48 Weeks | Vehicle (placebo) for 48 weeks |
| Total | Total of all reporting groups |

**Baseline Measures**

| | Terbinafine 24 Weeks | Vehicle 24 Weeks | Terbinafine 48 Weeks | Vehicle 48 Weeks | Total |
|---|---|---|---|---|---|
| Number of Participants [units: participants] | 133 | 130 | 135 | 128 | 526 |
| Age [units: participants] | | | | | |
| <=18 years | 0 | 0 | 0 | 1 | 1 |
| Between 18 and 65 years | 93 | 103 | 95 | 97 | 388 |
| >=65 years | 40 | 27 | 40 | 30 | 137 |
| Gender [units: participants] | | | | | |
| Female | 34 | 39 | 41 | 35 | 149 |

| | | | | | |
|---|---|---|---|---|---|
| **Male** | **99** | **91** | **94** | **93** | **377** |

## Outcome Measures

Hide All Outcome Measures

1. Primary: Efficacy Assessed by the Percentage of Participants With Complete Cure at the End of Study (Week 52) After Treating for 24 or 48 Weeks [ Time Frame: 52 weeks ]

| | |
|---|---|
| **Measure Type** | Primary |
| **Measure Title** | Efficacy Assessed by the Percentage of Participants With Complete Cure at the End of Study (Week 52) After Treating for 24 or 48 Weeks |
| **Measure Description** | Complete cure is defined as negative KOH microscopy and negative culture for dermatophytes and no residual involvement of the target toenail. |
| **Time Frame** | 52 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.** |
| Intent to treat (ITT) population, Last observation carried forward (LOCF) |

**Reporting Groups**

| | **Description** |
|---|---|
| **Terbinafine 24 Weeks** | Terbinafine hydrochloride (HCl) 10 % Nail Solution for Onychomycosis (NSO) for 24 weeks |
| **Vehicle 24 Weeks** | Vehicle (placebo) for 24 weeks |
| **Terbinafine 48 Weeks** | Terbinafine hydrochloride (HCl) 10 % Nail Solution for Onychomycosis (NSO) for 48 weeks |
| **Vehicle 48 Weeks** | Vehicle (placebo) for 48 weeks |

**Measured Values**

| | **Terbinafine 24 Weeks** | **Vehicle 24 Weeks** | **Terbinafine 48 Weeks** | **Vehicle 48 Weeks** |
|---|---|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **133** | **130** | **135** | **128** |
| **Efficacy Assessed by the Percentage of Participants With Complete Cure at the End of Study (Week 52) After Treating for 24 or 48 Weeks [units: Percentage of participants]** | **1.50** | **0.77** | **2.96** | **0** |

**No statistical analysis provided for Efficacy Assessed by the Percentage of Participants With Complete Cure at the End of Study (Week 52) After Treating for 24 or 48 Weeks**

2. Secondary: Efficacy Assessed by the Percentage of Participants With Mycological Cure at the End of Study After Treating Participants for 24 or 48 Weeks [ Time Frame: 52 weeks ]

| | |
|---|---|
| **Measure Type** | Secondary |
| **Measure Title** | Efficacy Assessed by the Percentage of Participants With Mycological Cure at the End of Study After Treating Participants for 24 or 48 Weeks |
| **Measure Description** | Mycological cure is defined as negative KOH microscopy and negative culture for dermatophytes. |

| | |
|---|---|
| **Time Frame** | 52 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.** |
| Intent to treat (ITT) population, Last observation carried forward (LOCF) |

**Reporting Groups**

| | **Description** |
|---|---|
| **Terbinafine 24 Weeks** | Terbinafine hydrochloride (HCl) 10 % Nail Solution for Onychomycosis (NSO) for 24 weeks |
| **Vehicle 24 Weeks** | Vehicle (placebo) for 24 weeks |
| **Terbinafine 48 Weeks** | Terbinafine hydrochloride (HCl) 10 % Nail Solution for Onychomycosis (NSO) for 48 weeks |
| **Vehicle 48 Weeks** | Vehicle (placebo) for 48 weeks |

**Measured Values**

| | **Terbinafine 24 Weeks** | **Vehicle 24 Weeks** | **Terbinafine 48 Weeks** | **Vehicle 48 Weeks** |
|---|---|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **133** | **130** | **135** | **128** |
| **Efficacy Assessed by the Percentage of Participants With Mycological Cure at the End of Study After Treating Participants for 24 or 48 Weeks [units: Percentage of participants]** | **15.04** | **6.15** | **22.22** | **7.81** |

**No statistical analysis provided for Efficacy Assessed by the Percentage of Participants With Mycological Cure at the End of Study After Treating Participants for 24 or 48 Weeks**

3. Secondary: Efficacy Assessed by the Percentage of Participants With Clinical Effectiveness at the End of Study After Treating Participants for 24 or 48 Weeks [ Time Frame: 52 weeks ]

| | |
|---|---|
| **Measure Type** | Secondary |
| **Measure Title** | Efficacy Assessed by the Percentage of Participants With Clinical Effectiveness at the End of Study After Treating Participants for 24 or 48 Weeks |
| **Measure Description** | Clinical effectiveness is defined as negative KOH microscopy and negative culture for dermatophytes and <= 10% residual involvement of the target toenail.<br>Clinical effectiveness was a composite binary variable defined as<br>• Yes" if:<br>  ◦ If mycological cure (negative KOH and negative culture for dermatophytes) and<br>  ◦ = 10% residual involvement of the target toenail<br>• No" if otherwise |
| **Time Frame** | 52 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.** |
| Intent to treat (ITT) population, Last observation carried forward (LOCF) |

**Reporting Groups**

| | Description |
|---|---|
| **Terbinafine 24 Weeks** | Terbinafine hydrochloride (HCl) 10 % Nail Solution for Onychomycosis (NSO) for 24 weeks |
| **Vehicle 24 Weeks** | Vehicle (placebo) for 24 weeks |
| **Terbinafine 48 Weeks** | Terbinafine hydrochloride (HCl) 10 % Nail Solution for Onychomycosis (NSO) for 48 weeks |
| **Vehicle 48 Weeks** | Vehicle (placebo) for 48 weeks |

**Measured Values**

| | Terbinafine 24 Weeks | Vehicle 24 Weeks | Terbinafine 48 Weeks | Vehicle 48 Weeks |
|---|---|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **133** | **130** | **135** | **128** |
| **Efficacy Assessed by the Percentage of Participants With Clinical Effectiveness at the End of Study After Treating Participants for 24 or 48 Weeks [units: Percentage of participants]** | **3.01** | **0.77** | **5.93** | **0.78** |

**No statistical analysis provided for Efficacy Assessed by the Percentage of Participants With Clinical Effectiveness at the End of Study After Treating Participants for 24 or 48 Weeks**

4. Secondary: Safety and Tolerability Assessed by the Number of Participants With Adverse Events [ Time Frame: 52 weeks ]

| | |
|---|---|
| **Measure Type** | Secondary |
| **Measure Title** | Safety and Tolerability Assessed by the Number of Participants With Adverse Events |
| **Measure Description** | Safety and tolerability data as assessed by the number of participants with Adverse Events (AE), Serious Adverse Events, Drug discontinuation due to an AE and death. Additional details can be found in the Adverse Event Section. |
| **Time Frame** | 52 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.** |
| Safety Population |

**Reporting Groups**

| | Description |
|---|---|
| **Terbinafine 24 Weeks** | Terbinafine hydrochloride (HCl) 10 % Nail Solution for Onychomycosis (NSO) for 24 weeks |
| **Vehicle 24 Weeks** | Vehicle (placebo) for 24 weeks |
| **Terbinafine 48 Weeks** | Terbinafine hydrochloride (HCl) 10 % Nail Solution for Onychomycosis (NSO) for 48 weeks |
| **Vehicle 48 Weeks** | Vehicle (placebo) for 48 weeks |

**Measured Values**

| | Terbinafine 24 Weeks | Vehicle 24 Weeks | Terbinafine 48 Weeks | Vehicle 48 Weeks |
|---|---|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **131** | **129** | **134** | **126** |
| **Safety and Tolerability Assessed by the Number of Participants** | | | | |

| With Adverse Events [units: Number of participants] | | | | |
|---|---|---|---|---|
| At least 1 AE | 80 | 72 | 94 | 87 |
| At least 1 SAE | 8 | 3 | 9 | 7 |
| Study drug discontinued due to an AE | 0 | 1 | 1 | 0 |
| Death | 0 | 0 | 1 | 0 |

**No statistical analysis provided for Safety and Tolerability Assessed by the Number of Participants With Adverse Events**

## Serious Adverse Events

Hide Serious Adverse Events

| | |
|---|---|
| **Time Frame** | 52 weeks |
| **Additional Description** | Safety population consisting of all participants who had at least one dose of study drug and had at least one post-baseline safety assessment. |

**Reporting Groups**

| | Description |
|---|---|
| **Terbinafine 24 Weeks** | Terbinafine hydrochloride (HCl) 10 % Nail Solution for Onychomycosis (NSO) for 24 weeks |
| **Vehicle 24 Weeks** | Vehicle (placebo) for 24 weeks |
| **Terbinafine 48 Weeks** | Terbinafine hydrochloride (HCl) 10 % Nail Solution for Onychomycosis (NSO) for 48 weeks |
| **Vehicle 48 Weeks** | Vehicle (placebo) for 48 weeks |

**Serious Adverse Events**

| | Terbinafine 24 Weeks | Vehicle 24 Weeks | Terbinafine 48 Weeks | Vehicle 48 Weeks |
|---|---|---|---|---|
| **Total, serious adverse events** | | | | |
| # participants affected / at risk | 8/131 (6.11%) | 3/129 (2.33%) | 9/134 (6.72%) | 7/126 (5.56%) |
| **Cardiac disorders** | | | | |
| Acute coronary syndrome † 1 | | | | |
| # participants affected / at risk | 1/131 (0.76%) | 0/129 (0.00%) | 0/134 (0.00%) | 0/126 (0.00%) |
| Angina pectoris † 1 | | | | |
| # participants affected / at risk | 1/131 (0.76%) | 0/129 (0.00%) | 0/134 (0.00%) | 0/126 (0.00%) |
| Arrhythmia † 1 | | | | |
| # participants affected / at risk | 1/131 (0.76%) | 0/129 (0.00%) | 0/134 (0.00%) | 0/126 (0.00%) |
| Myocardial infarction † 1 | | | | |
| # participants affected / at risk | 1/131 (0.76%) | 0/129 (0.00%) | 1/134 (0.75%) | 0/126 (0.00%) |
| Tachycardia † 1 | | | | |
| # participants affected / at risk | 0/131 (0.00%) | 0/129 (0.00%) | 0/134 (0.00%) | 1/126 (0.79%) |
| **Gastrointestinal disorders** | | | | |
| Constipation † 1 | | | | |
| # participants affected / at risk | 0/131 (0.00%) | 0/129 (0.00%) | 0/134 (0.00%) | 1/126 (0.79%) |
| Gastric ulcer † 1 | | | | |
| # participants affected / at risk | 0/131 (0.00%) | 1/129 (0.78%) | 0/134 (0.00%) | 0/126 (0.00%) |

| | | | | |
|---|---|---|---|---|
| **Infections and infestations** | | | | |
| **Cellulitis † 1** | | | | |
| **# participants affected / at risk** | **0/131 (0.00%)** | **0/129 (0.00%)** | **1/134 (0.75%)** | **0/126 (0.00%)** |
| **Pneumonia † 1** | | | | |
| **# participants affected / at risk** | **0/131 (0.00%)** | **0/129 (0.00%)** | **0/134 (0.00%)** | **1/126 (0.79%)** |
| **Injury, poisoning and procedural complications** | | | | |
| **Near drowning † 1** | | | | |
| **# participants affected / at risk** | **0/131 (0.00%)** | **0/129 (0.00%)** | **1/134 (0.75%)** | **0/126 (0.00%)** |
| **Subdural haematoma † 1** | | | | |
| **# participants affected / at risk** | **0/131 (0.00%)** | **0/129 (0.00%)** | **1/134 (0.75%)** | **0/126 (0.00%)** |
| **Metabolism and nutrition disorders** | | | | |
| **Hypocalcaemia † 1** | | | | |
| **# participants affected / at risk** | **0/131 (0.00%)** | **0/129 (0.00%)** | **0/134 (0.00%)** | **1/126 (0.79%)** |
| **Musculoskeletal and connective tissue disorders** | | | | |
| **Back pain † 1** | | | | |
| **# participants affected / at risk** | **0/131 (0.00%)** | **0/129 (0.00%)** | **1/134 (0.75%)** | **1/126 (0.79%)** |
| **Intervertebral disc protrusion † 1** | | | | |
| **# participants affected / at risk** | **0/131 (0.00%)** | **0/129 (0.00%)** | **1/134 (0.75%)** | **0/126 (0.00%)** |
| **Osteoarthritis † 1** | | | | |
| **# participants affected / at risk** | **0/131 (0.00%)** | **0/129 (0.00%)** | **1/134 (0.75%)** | **0/126 (0.00%)** |
| **Neoplasms benign, malignant and unspecified (incl cysts and polyps)** | | | | |
| **Bladder cancer † 1** | | | | |
| **# participants affected / at risk** | **1/131 (0.76%)** | **0/129 (0.00%)** | **0/134 (0.00%)** | **0/126 (0.00%)** |
| **Bladder neoplasm † 1** | | | | |
| **# participants affected / at risk** | **1/131 (0.76%)** | **0/129 (0.00%)** | **0/134 (0.00%)** | **0/126 (0.00%)** |
| **Breast cancer † 1** | | | | |
| **# participants affected / at risk** | **0/131 (0.00%)** | **0/129 (0.00%)** | **1/134 (0.75%)** | **0/126 (0.00%)** |
| **Cervix carcinoma † 1** | | | | |
| **# participants affected / at risk** | **0/131 (0.00%)** | **0/129 (0.00%)** | **1/134 (0.75%)** | **0/126 (0.00%)** |
| **Malignant melanoma † 1** | | | | |
| **# participants affected / at risk** | **1/131 (0.76%)** | **0/129 (0.00%)** | **0/134 (0.00%)** | **0/126 (0.00%)** |
| **Malignant melanoma in situ † 1** | | | | |
| **# participants affected / at risk** | **0/131 (0.00%)** | **0/129 (0.00%)** | **0/134 (0.00%)** | **1/126 (0.79%)** |
| **Meningioma † 1** | | | | |
| **# participants affected / at risk** | **0/131 (0.00%)** | **1/129 (0.78%)** | **0/134 (0.00%)** | **0/126 (0.00%)** |
| **Prostate cancer † 1** | | | | |
| **# participants affected / at risk** | **2/131 (1.53%)** | **0/129 (0.00%)** | **0/134 (0.00%)** | **0/126 (0.00%)** |
| **Nervous system disorders** | | | | |
| **Sciatica † 1** | | | | |
| **# participants affected / at risk** | **0/131 (0.00%)** | **0/129 (0.00%)** | **0/134 (0.00%)** | **1/126 (0.79%)** |
| **Renal and urinary disorders** | | | | |
| **Bladder prolapse † 1** | | | | |
| **# participants affected / at risk** | **0/131 (0.00%)** | **0/129 (0.00%)** | **0/134 (0.00%)** | **1/126 (0.79%)** |

| | | | | |
|---|---|---|---|---|
| Dysuria † 1 | | | | |
| # participants affected / at risk | 0/131 (0.00%) | 0/129 (0.00%) | 0/134 (0.00%) | 1/126 (0.79%) |
| Micturition disorder † 1 | | | | |
| # participants affected / at risk | 0/131 (0.00%) | 0/129 (0.00%) | 0/134 (0.00%) | 1/126 (0.79%) |
| Renal failure † 1 | | | | |
| # participants affected / at risk | 0/131 (0.00%) | 1/129 (0.78%) | 0/134 (0.00%) | 0/126 (0.00%) |
| Reproductive system and breast disorders | | | | |
| Epididymitis † 1 | | | | |
| # participants affected / at risk | 0/131 (0.00%) | 0/129 (0.00%) | 0/134 (0.00%) | 1/126 (0.79%) |
| Respiratory, thoracic and mediastinal disorders | | | | |
| Dyspnoea † 1 | | | | |
| # participants affected / at risk | 0/131 (0.00%) | 0/129 (0.00%) | 1/134 (0.75%) | 0/126 (0.00%) |

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

## Other Adverse Events

Hide Other Adverse Events

| | |
|---|---|
| **Time Frame** | 52 weeks |
| **Additional Description** | Safety population consisting of all participants who had at least one dose of study drug and had at least one post-baseline safety assessment. |

### Frequency Threshold

| | |
|---|---|
| **Threshold above which other adverse events are reported** | 5% |

### Reporting Groups

| | Description |
|---|---|
| **Terbinafine 24 Weeks** | Terbinafine hydrochloride (HCl) 10 % Nail Solution for Onychomycosis (NSO) for 24 weeks |
| **Vehicle 24 Weeks** | Vehicle (placebo) for 24 weeks |
| **Terbinafine 48 Weeks** | Terbinafine hydrochloride (HCl) 10 % Nail Solution for Onychomycosis (NSO) for 48 weeks |
| **Vehicle 48 Weeks** | Vehicle (placebo) for 48 weeks |

### Other Adverse Events

| | Terbinafine 24 Weeks | Vehicle 24 Weeks | Terbinafine 48 Weeks | Vehicle 48 Weeks |
|---|---|---|---|---|
| Total, other (not including serious) adverse events | | | | |
| # participants affected / at risk | 37/131 (28.24%) | 38/129 (29.46%) | 54/134 (40.30%) | 52/126 (41.27%) |
| Infections and infestations | | | | |
| Influenza † 1 | | | | |
| # participants affected / at risk | 2/131 (1.53%) | 1/129 (0.78%) | 13/134 (9.70%) | 10/126 (7.94%) |
| Nasopharyngitis † 1 | | | | |
| # participants affected / at risk | 13/131 (9.92%) | 11/129 (8.53%) | 15/134 (11.19%) | 15/126 (11.90%) |
| Sinusitis † 1 | | | | |

| | | | | |
|---|---|---|---|---|
| **# participants affected / at risk** | **3/131 (2.29%)** | **0/129 (0.00%)** | **4/134 (2.99%)** | **7/126 (5.56%)** |
| **Upper respiratory tract infection † 1** | | | | |
| **# participants affected / at risk** | **4/131 (3.05%)** | **4/129 (3.10%)** | **4/134 (2.99%)** | **10/126 (7.94%)** |
| **Musculoskeletal and connective tissue disorders** | | | | |
| **Back pain † 1** | | | | |
| **# participants affected / at risk** | **8/131 (6.11%)** | **7/129 (5.43%)** | **6/134 (4.48%)** | **12/126 (9.52%)** |
| **Nervous system disorders** | | | | |
| **Headache † 1** | | | | |
| **# participants affected / at risk** | **21/131 (16.03%)** | **21/129 (16.28%)** | **28/134 (20.90%)** | **23/126 (18.25%)** |
| **Vascular disorders** | | | | |
| **Hypertension † 1** | | | | |
| **# participants affected / at risk** | **1/131 (0.76%)** | **3/129 (2.33%)** | **8/134 (5.97%)** | **4/126 (3.17%)** |

† 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** |
|---|
| 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.<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 **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.<br>Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.<br>☑ **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: | External Affairs, Novartis Pharmaceuticals |
| ClinicalTrials.gov Identifier: | NCT00443820 History of Changes |
| Other Study ID Numbers: | **CSFO327N2302** |
| Study First Received: | March 2, 2007 |
| Results First Received: | January 19, 2011 |
| Last Updated: | March 22, 2011 |
| Health Authority: | United States: Food and Drug Administration<br>France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis)<br>Germany: Federal Institute for Drugs and Medical Devices |