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Trial record **1 of 1** for: CSFO327N2301

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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 (Responsible Party):
Novartis (Novartis Pharmaceuticals)

ClinicalTrials.gov Identifier:
NCT00443898

First received: March 5, 2007
Last updated: May 1, 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: January 19, 2011

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
Condition:	Onychomycosis
Interventions:	Drug: terbinafine 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
No text entered.

Pre-Assignment Details

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

Reporting Groups

	Description
Terbinafine 24 w	Active terbinafine hydrochloride (HCl) 10 % Nail Solution for Onychomycosis (NSO) applied once daily for 24 weeks
Vehicle 24 w	vehicle (placebo) applied once daily for 24 weeks
Terbinafine 48 w	Active terbinafine hydrochloride (HCl) 10 % Nail Solution for Onychomycosis (NSO) applied once daily for 48 weeks
Vehicle 48 w	vehicle (placebo) applied once daily for 48 weeks

Participant Flow: Overall Study

	Terbinafine 24 w	**Vehicle 24 w**	**Terbinafine 48 w**	**Vehicle 48 w**

STARTED	**126**	**128**	**136**	**128**
COMPLETED	**102**	**103**	**107**	**110**
NOT COMPLETED	**24**	**25**	**29**	**18**
Adverse Event	**0**	**0**	**1**	**1**
Lack of Efficacy	**2**	**3**	**3**	**1**
Protocol Violation	**1**	**1**	**1**	**0**
Withdrawal by Subject	**11**	**10**	**10**	**6**
Lost to Follow-up	**10**	**10**	**14**	**10**
Death	**0**	**1**	**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
Terbinafine 24 w	Active terbinafine hydrochloride (HCl) 10 % Nail Solution for Onychomycosis (NSO) applied once daily for 24 weeks
Vehicle 24 w	vehicle (placebo) applied once daily for 24 weeks
Terbinafine 48 w	Active terbinafine hydrochloride (HCl) 10 % Nail Solution for Onychomycosis (NSO) applied once daily for 48 weeks
Vehicle 48 w	vehicle (placebo) applied once daily for 48 weeks
Total	Total of all reporting groups

Baseline Measures

	Terbinafine 24 w	**Vehicle 24 w**	**Terbinafine 48 w**	**Vehicle 48 w**	**Total**
Number of Participants [units: participants]	**126**	**128**	**136**	**128**	**518**
Age [units: participants]					
<=18 years	**0**	**0**	**0**	**0**	**0**
Between 18 and 65 years	**107**	**101**	**116**	**100**	**424**
>=65 years	**19**	**27**	**20**	**28**	**94**
Gender [units: participants]					
Female	**25**	**29**	**26**	**27**	**107**
Male	**101**	**99**	**110**	**101**	**411**

Outcome Measures

Hide All Outcome Measures

1. Primary: Efficacy Assessed by Complete Cure Rate 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 Complete Cure Rate 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. The complete cure was a composite binary variable defined as • Yes" if: ◦ Mycological cure (negative KOH and negative culture for dermatophytes) and ◦ No residual involvement of the target toenail • 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.
All participants were included in the intention to treat (ITT) population, defined as all participants who were randomized and received study drug. The Last Observation was Carried Forward (LOCF).

Reporting Groups

	Description
Terbinafine 24 w	Active terbinafine hydrochloride (HCl) 10 % Nail Solution for Onychomycosis (NSO) applied once daily for 24 weeks
Vehicle 24 w	vehicle (placebo) applied once daily for 24 weeks
Terbinafine 48 w	Active terbinafine hydrochloride (HCl) 10 % Nail Solution for Onychomycosis (NSO) applied once daily for 48 weeks
Vehicle 48 w	vehicle (placebo) applied once daily for 48 weeks

Measured Values

	Terbinafine 24 w	**Vehicle 24 w**	**Terbinafine 48 w**	**Vehicle 48 w**
Number of Participants Analyzed [units: participants]	**126**	**128**	**136**	**128**
Efficacy Assessed by Complete Cure Rate at the End of Study (Week 52) After Treating for 24 or 48 Weeks. [units: Percentage of Participants]	**0.79**	**0.78**	**1.47**	**0.00**

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

2. Secondary: Efficacy Assessed by Mycological Cure (Negative Culture and Negative KOH Microscopy) at the End of Study After Treating Patients for 24 or 48 Weeks. [Time Frame: 52 weeks]

Measure Type	Secondary
Measure Title	Efficacy Assessed by Mycological Cure (Negative Culture and Negative KOH Microscopy) at the End of Study After Treating Patients for 24 or 48 Weeks.
Measure Description	Mycological cure is defined as negative KOH microscopy and negative culture for dermatophytes. Mycological cure was a composite binary variable defined as • Yes"if : ◦ Negative microscopy and

	◦ Negative culture for dermatophytes • 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.
All participants were included in the intention to treat (ITT) population, defined as all participants who were randomized and received study drug. The Last Observation was Carried Forward (LOCF).

Reporting Groups

	Description
Terbinafine 24 w	Active terbinafine hydrochloride (HCl) 10 % Nail Solution for Onychomycosis (NSO) applied once daily for 24 weeks
Vehicle 24 w	vehicle (placebo) applied once daily for 24 weeks
Terbinafine 48 w	Active terbinafine hydrochloride (HCl) 10 % Nail Solution for Onychomycosis (NSO) applied once daily for 48 weeks
Vehicle 48 w	vehicle (placebo) applied once daily for 48 weeks

Measured Values

	Terbinafine 24 w	**Vehicle 24 w**	**Terbinafine 48 w**	**Vehicle 48 w**
Number of Participants Analyzed [units: participants]	**126**	**128**	**136**	**128**
Efficacy Assessed by Mycological Cure (Negative Culture and Negative KOH Microscopy) at the End of Study After Treating Patients for 24 or 48 Weeks. [units: Percentage of Participants]	**10.32**	**6.25**	**15.44**	**3.13**

No statistical analysis provided for Efficacy Assessed by Mycological Cure (Negative Culture and Negative KOH Microscopy) at the End of Study After Treating Patients for 24 or 48 Weeks.

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

Measure Type	Secondary
Measure Title	Efficacy Assessed by Clinical Efficacy at the End of Study After Treating Patients 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. Clinical effectiveness was a composite binary variable defined as • Yes" if ◦ Mycological cure (negative KOH and negative culture for dermatophytes) and ◦ = 10% residual involvement of the target toenail • 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.

All participants were included in the intention to treat (ITT) population, defined as all participants who were randomized and received study drug. The Last Observation was Carried Forward (LOCF).

Reporting Groups

	Description
Terbinafine 24 w	Active terbinafine hydrochloride (HCl) 10 % Nail Solution for Onychomycosis (NSO) applied once daily for 24 weeks
Vehicle 24 w	vehicle (placebo) applied once daily for 24 weeks
Terbinafine 48 w	Active terbinafine hydrochloride (HCl) 10 % Nail Solution for Onychomycosis (NSO) applied once daily for 48 weeks
Vehicle 48 w	vehicle (placebo) applied once daily for 48 weeks

Measured Values

	Terbinafine 24 w	Vehicle 24 w	Terbinafine 48 w	Vehicle 48 w
Number of Participants Analyzed [units: participants]	**126**	**128**	**136**	**128**
Efficacy Assessed by Clinical Efficacy at the End of Study After Treating Patients for 24 or 48 Weeks. [units: Percentage of Participants]	**1.59**	**2.34**	**3.68**	**1.56**

No statistical analysis provided for Efficacy Assessed by Clinical Efficacy at the End of Study After Treating Patients for 24 or 48 Weeks.

4. Secondary: Number of Participants Assessed With Adverse Events and Serious Adverse Events [Time Frame: 52 weeks]

Measure Type	Secondary
Measure Title	Number of Participants Assessed With Adverse Events and Serious Adverse Events
Measure Description	An adverse event (AE) is any adverse change in health or side effect that occurs while the participant is receiving the treatment or within a previously specified period of time after the treatment has been completed. A Serious Adverse Event (SAE) is any untoward medical occurrence that results in death, is life-threatening requires, inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, is a congenital anomaly/birth defect, or requires intervention to prevent permanent impairment or damage.
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 was defined as all participants who received at least one dose of study drug and had at least one post-baseline safety assessment. All except 4 participants who were randomized to the vehicle 24 w group and one participant randomized to the terbinafine 48 w group, were included in the safety population.

Reporting Groups

	Description
Terbinafine 24 w	Active terbinafine hydrochloride (HCl) 10 % Nail Solution for Onychomycosis (NSO) applied once daily for 24 weeks
Vehicle 24 w	vehicle (placebo) applied once daily for 24 weeks
Terbinafine 48 w	Active terbinafine hydrochloride (HCl) 10 % Nail Solution for Onychomycosis (NSO) applied once daily for 48 weeks
Vehicle 48 w	vehicle (placebo) applied once daily for 48 weeks

Measured Values

	Terbinafine 24 w	Vehicle 24 w	Terbinafine 48 w	Vehicle 48 w
Number of Participants Analyzed [units: participants]	**126**	**124**	**135**	**128**
Number of Participants Assessed With Adverse Events and Serious Adverse Events [units: Participants]	**126**	**124**	**135**	**128**

No statistical analysis provided for Number of Participants Assessed With Adverse Events and Serious Adverse Events

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	52 weeks
Additional Description	Safety Population was defined as all participants who received at least one dose of study drug and had at least one post-baseline safety assessment. All except 4 participants who were randomized to the vehicle 24 w group and one participant randomized to the terbinafine 48 w group, were included in the safety population.

Reporting Groups

	Description
Terbinafine 24 w	Active terbinafine hydrochloride (HCl) 10 % Nail Solution for Onychomycosis (NSO) applied once daily for 24 weeks
Vehicle 24 w	vehicle (placebo) applied once daily for 24 weeks
Terbinafine 48 w	Active terbinafine hydrochloride (HCl) 10 % Nail Solution for Onychomycosis (NSO) applied once daily for 48 weeks
Vehicle 48 w	vehicle (placebo) applied once daily for 48 weeks

Serious Adverse Events

	Terbinafine 24 w	Vehicle 24 w	Terbinafine 48 w	Vehicle 48 w
Total, serious adverse events				
# participants affected / at risk	**2/126 (1.59%)**	**7/124 (5.65%)**	**7/135 (5.19%)**	**4/128 (3.13%)**
Cardiac disorders				
Cardiac failure congestive † 1				
# participants affected / at risk	**0/126 (0.00%)**	**0/124 (0.00%)**	**0/135 (0.00%)**	**1/128 (0.78%)**
Gastrointestinal disorders				
Gastric ulcer perforation † 1				
# participants affected / at risk	**0/126 (0.00%)**	**0/124 (0.00%)**	**1/135 (0.74%)**	**0/128 (0.00%)**
General disorders				
Accidental death † 1				
# participants affected / at risk	**0/126 (0.00%)**	**1/124 (0.81%)**	**0/135 (0.00%)**	**0/128 (0.00%)**
Chest discomfort † 1				
# participants affected / at risk	**0/126 (0.00%)**	**0/124 (0.00%)**	**1/135 (0.74%)**	**0/128 (0.00%)**
Infections and infestations				
Appendicitis † 1				
# participants affected / at risk	**0/126 (0.00%)**	**0/124 (0.00%)**	**2/135 (1.48%)**	**0/128 (0.00%)**

Cellulitis † 1				
# participants affected / at risk	**0/126 (0.00%)**	**0/124 (0.00%)**	**0/135 (0.00%)**	**1/128 (0.78%)**
Pneumonia † 1				
# participants affected / at risk	**0/126 (0.00%)**	**1/124 (0.81%)**	**0/135 (0.00%)**	**0/128 (0.00%)**
Injury, poisoning and procedural complications				
Lower limb fracture † 1				
# participants affected / at risk	**0/126 (0.00%)**	**0/124 (0.00%)**	**1/135 (0.74%)**	**1/128 (0.78%)**
Tendon rupture † 1				
# participants affected / at risk	**0/126 (0.00%)**	**1/124 (0.81%)**	**0/135 (0.00%)**	**0/128 (0.00%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Endometrial cancer † 1				
# participants affected / at risk	**0/126 (0.00%)**	**1/124 (0.81%)**	**0/135 (0.00%)**	**0/128 (0.00%)**
Metastatic malignant melanoma † 1				
# participants affected / at risk	**0/126 (0.00%)**	**1/124 (0.81%)**	**0/135 (0.00%)**	**0/128 (0.00%)**
Multiple myeloma † 1				
# participants affected / at risk	**0/126 (0.00%)**	**0/124 (0.00%)**	**0/135 (0.00%)**	**1/128 (0.78%)**
Prostate cancer † 1				
# participants affected / at risk	**1/126 (0.79%)**	**1/124 (0.81%)**	**1/135 (0.74%)**	**0/128 (0.00%)**
Nervous system disorders				
Cerebral haemorrhage † 1				
# participants affected / at risk	**0/126 (0.00%)**	**0/124 (0.00%)**	**1/135 (0.74%)**	**0/128 (0.00%)**
Convulsion † 1				
# participants affected / at risk	**1/126 (0.79%)**	**0/124 (0.00%)**	**0/135 (0.00%)**	**0/128 (0.00%)**
Headache † 1				
# participants affected / at risk	**0/126 (0.00%)**	**0/124 (0.00%)**	**1/135 (0.74%)**	**0/128 (0.00%)**
Syncope † 1				
# participants affected / at risk	**0/126 (0.00%)**	**1/124 (0.81%)**	**0/135 (0.00%)**	**0/128 (0.00%)**
Syncope vasovagal † 1				
# participants affected / at risk	**0/126 (0.00%)**	**1/124 (0.81%)**	**0/135 (0.00%)**	**0/128 (0.00%)**
Respiratory, thoracic and mediastinal disorders				
Dyspnoea † 1				
# participants affected / at risk	**0/126 (0.00%)**	**0/124 (0.00%)**	**1/135 (0.74%)**	**0/128 (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 was defined as all participants who received at least one dose of study drug and had at least one post-baseline safety assessment. All except 4 participants who were randomized to the vehicle 24 w group and one participant randomized to the terbinafine 48 w group, were included in the safety population.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Terbinafine 24 w	Active terbinafine hydrochloride (HCl) 10 % Nail Solution for Onychomycosis (NSO) applied once daily for 24 weeks
Vehicle 24 w	vehicle (placebo) applied once daily for 24 weeks
Terbinafine 48 w	Active terbinafine hydrochloride (HCl) 10 % Nail Solution for Onychomycosis (NSO) applied once daily for 48 weeks
Vehicle 48 w	vehicle (placebo) applied once daily for 48 weeks

Other Adverse Events

	Terbinafine 24 w	Vehicle 24 w	Terbinafine 48 w	Vehicle 48 w
Total, other (not including serious) adverse events				
# participants affected / at risk	**35/126 (27.78%)**	**38/124 (30.65%)**	**47/135 (34.81%)**	**56/128 (43.75%)**
General disorders				
Influenza like illness † 1				
# participants affected / at risk	**2/126 (1.59%)**	**1/124 (0.81%)**	**0/135 (0.00%)**	**8/128 (6.25%)**
Infections and infestations				
Nasopharyngitis † 1				
# participants affected / at risk	**7/126 (5.56%)**	**9/124 (7.26%)**	**18/135 (13.33%)**	**18/128 (14.06%)**
Upper respiratory tract infection † 1				
# participants affected / at risk	**4/126 (3.17%)**	**6/124 (4.84%)**	**8/135 (5.93%)**	**8/128 (6.25%)**
Musculoskeletal and connective tissue disorders				
Back pain † 1				
# participants affected / at risk	**7/126 (5.56%)**	**7/124 (5.65%)**	**9/135 (6.67%)**	**10/128 (7.81%)**
Nervous system disorders				
Headache † 1				
# participants affected / at risk	**23/126 (18.25%)**	**24/124 (19.35%)**	**23/135 (17.04%)**	**29/128 (22.66%)**

† 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:

☐ 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 (Novartis Pharmaceuticals)
ClinicalTrials.gov Identifier:	NCT00443898 History of Changes
Other Study ID Numbers:	**CSFO327N2301**
Study First Received:	March 5, 2007
Results First Received:	January 19, 2011
Last Updated:	May 1, 2012
Health Authority:	United States: Food and Drug Administration Canada: Health Canada Iceland: Ministry of Health and Social Security