Trial record **1 of 1** for: CSFO327N2303
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Efficacy, Safety and Tolerability of Topical 10% Terbinafine Hydrogen Chloride Versus 5% Amorolfine Nail Lacquer in Patients With Mild to Moderate Toenail Onychomycosis

This study has been completed.

Sponsor:
Novartis

Information provided by:
Novartis

ClinicalTrials.gov Identifier:
NCT00459537

First received: April 10, 2007
Last updated: May 3, 2011
Last verified: May 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; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Onychomycosis
Interventions:	Drug: terbinafine hydrogen chloride Drug: amorolfine nail lacquer

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	10% terbinafine hydrogen chloride (72.6 mg/ml nail lacquer). Patients applied one layer of the study medication once daily for 48 weeks, preferably at bedtime, to all affected toenails and allowed to dry.
Amorolfine	5% amorolfine nail lacquer. Patients applied study medication twice weekly for 48 weeks to all affected toenails.

Participant Flow: Overall Study

	Terbinafine	**Amorolfine**
STARTED	**507**	**522**
Safety Population	**493** [1]	**512**

COMPLETED	**441**	**446**
NOT COMPLETED	**66**	**76**
Adverse Event	**1**	**6**
Lack of Efficacy	**10**	**11**
Withdrawal by Subject	**20**	**26**
Lost to Follow-up	**27**	**30**
Administrative problems	**3**	**0**
Protocol Violation	**4**	**3**
Missing	**1**	**0**

[1] Participants who had at least one dose of study drug and one post-baseline safety assessment.

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	10% terbinafine hydrogen chloride (72.6 mg/ml nail lacquer). Patients applied one layer of the study medication once daily for 48 weeks, preferably at bedtime, to all affected toenails and allowed to dry.
Amorolfine	5% amorolfine nail lacquer. Patients applied study medication twice weekly for 48 weeks to all affected toenails.
Total	Total of all reporting groups

Baseline Measures

	Terbinafine	**Amorolfine**	**Total**
Number of Participants [units: participants]	**507**	**522**	**1029**
Age [units: participants]			
<=18 years	**0**	**1**	**1**
Between 18 and 65 years	**425**	**410**	**835**
>=65 years	**82**	**111**	**193**
Gender [units: participants]			
Female	**158**	**150**	**308**
Male	**349**	**372**	**721**

Outcome Measures

Hide All Outcome Measures

1. Primary: Percentage of Participants With Complete Cure at the End of Study After Treating Participants for 48 Weeks [Time Frame: Week

52]

Measure Type	Primary
Measure Title	Percentage of Participants With Complete Cure at the End of Study After Treating Participants for 48 Weeks
Measure Description	Complete cure is defined as negative potassium hydroxide (KOH) microscopy and negative culture for dermatophytes and no residual involvement of the target toenail.
Time Frame	Week 52
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 Intent-to-treat population (ITT) population consisted of all patients who were randomized and dispensed study drug. Last Observation Carried Forward (LOCF)

Reporting Groups

	Description
Terbinafine	10% terbinafine hydrogen chloride (72.6 mg/ml nail lacquer). Patients applied one layer of the study medication once daily for 48 weeks, preferably at bedtime, to all affected toenails and allowed to dry.
Amorolfine	5% amorolfine nail lacquer. Patients applied study medication twice weekly for 48 weeks to all affected toenails.

Measured Values

	Terbinafine	**Amorolfine**
Number of Participants Analyzed [units: participants]	**507**	**522**
Percentage of Participants With Complete Cure at the End of Study After Treating Participants for 48 Weeks [units: Percentage of participants]	**1.18**	**0.96**

No statistical analysis provided for Percentage of Participants With Complete Cure at the End of Study After Treating Participants for 48 Weeks

2. Primary: Percentage of Participants With Complete Cure at the End of Study After Treating Participants for 48 Weeks. [Time Frame: Week 52]

Measure Type	Primary
Measure Title	Percentage of Participants With Complete Cure at the End of Study After Treating Participants for 48 Weeks.
Measure Description	Complete cure is defined as negative potassium hydroxide (KOH) microscopy and negative culture for dermatophytes and no residual involvement of the target toenail.
Time Frame	Week 52
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 Per-protocol population (PP) consisted of ITT patients who completed the study without protocol deviations that led to exclusion according to criteria defined before database lock The per-protocol population was used to provide confirmation of efficacy findings from the ITT population. Last Observation Carried Forward (LOCF).

Reporting Groups

	Description

Terbinafine	10% terbinafine hydrogen chloride (72.6 mg/ml nail lacquer). Patients applied one layer of the study medication once daily for 48 weeks, preferably at bedtime, to all affected toenails and allowed to dry.
Amorolfine	5% amorolfine nail lacquer. Patients applied study medication twice weekly for 48 weeks to all affected toenails.

Measured Values

	Terbinafine	Amorolfine
Number of Participants Analyzed [units: participants]	**260**	**266**
Percentage of Participants With Complete Cure at the End of Study After Treating Participants for 48 Weeks. [units: Percentage of participants]	**1.15**	**0.38**

No statistical analysis provided for Percentage of Participants With Complete Cure at the End of Study After Treating Participants for 48 Weeks.

3. Secondary: Percentage of Participants With Clinical Effectiveness at the End of Study After Treating Patients for 48 Weeks. [Time Frame: Week 52]

Measure Type	Secondary
Measure Title	Percentage of Participants With Clinical Effectiveness at the End of Study After Treating Patients for 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.
Time Frame	Week 52
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 population, Last Observation Carried Forward (LOCF)

Reporting Groups

	Description
Terbinafine	10% terbinafine hydrogen chloride (72.6 mg/ml nail lacquer). Patients applied one layer of the study medication once daily for 48 weeks, preferably at bedtime, to all affected toenails and allowed to dry.
Amorolfine	5% amorolfine nail lacquer. Patients applied study medication twice weekly for 48 weeks to all affected toenails.

Measured Values

	Terbinafine	Amorolfine
Number of Participants Analyzed [units: participants]	**507**	**522**
Percentage of Participants With Clinical Effectiveness at the End of Study After Treating Patients for 48 Weeks. [units: Percentage of participants]	**4.54**	**3.83**

No statistical analysis provided for Percentage of Participants With Clinical Effectiveness at the End of Study After Treating Patients for 48 Weeks.

4. Secondary: Percentage of Participants With Mycological Cure at End of Study After Treating Patients for 48 Weeks [Time Frame: Week 52]

Measure Type	Secondary
Measure Title	Percentage of Participants With Mycological Cure at End of Study After Treating Patients for 48 Weeks
Measure Description	Mycological cure is defined as negative KOH microscopy and negative culture for dermatophytes
Time Frame	Week 52
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 population, Last Observation Carried Forward (LOCF)

Reporting Groups

	Description
Terbinafine	10% terbinafine hydrogen chloride (72.6 mg/ml nail lacquer). Patients applied one layer of the study medication once daily for 48 weeks, preferably at bedtime, to all affected toenails and allowed to dry.
Amorolfine	5% amorolfine nail lacquer. Patients applied study medication twice weekly for 48 weeks to all affected toenails.

Measured Values

	Terbinafine	**Amorolfine**
Number of Participants Analyzed [units: participants]	**507**	**522**
Percentage of Participants With Mycological Cure at End of Study After Treating Patients for 48 Weeks [units: Percentage of participants]	**16.17**	**15.71**

No statistical analysis provided for Percentage of Participants With Mycological Cure at End of Study After Treating Patients for 48 Weeks

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

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 or SAE and death. Additional details can be found in the Adverse Event Section.
Time Frame	Week 52
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 population consisted of all patients that received at least one dose of study drug and had at least one post-baseline safety assessment.

Reporting Groups

	Description
Terbinafine	10% terbinafine hydrogen chloride (72.6 mg/ml nail lacquer). Patients applied one layer of the study medication once daily for 48 weeks, preferably at bedtime, to all affected toenails and allowed to dry.
Amorolfine	5% amorolfine nail lacquer. Patients applied study medication twice weekly for 48 weeks to all affected toenails.

Measured Values

	Terbinafine	Amorolfine
Number of Participants Analyzed [units: participants]	**493**	**512**
Safety and Tolerability Assessed by the Number of Participants With Adverse Events [units: Participants]		
At least 1 AE	**285**	**291**
AE suspected related to study drug	**11**	**7**
At least 1 SAE	**9**	**18**
SAE suspected related to study drug	**0**	**0**
Death	**0**	**0**
Drug discontinuation due to an AE	**1**	**5**

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 patients who received at least one dose of study drug and had at least one post-baseline safety assessment.

Reporting Groups

	Description
Terbinafine	10% terbinafine hydrogen chloride (72.6 mg/ml nail lacquer). Patients applied one layer of the study medication once daily for 48 weeks, preferably at bedtime, to all affected toenails and allowed to dry.
Amorolfine	5% amorolfine nail lacquer. Patients applied study medication twice weekly for 48 weeks to all affected toenails.

Serious Adverse Events

	Terbinafine	Amorolfine
Total, serious adverse events		
# participants affected / at risk	**9/493 (1.83%)**	**18/512 (3.52%)**
Blood and lymphatic system disorders		
Lymphadenopathy † 1		
# participants affected / at risk	**1/493 (0.20%)**	**0/512 (0.00%)**
Cardiac disorders		
Arteriosclerosis coronary artery † 1		
# participants affected / at risk	**0/493 (0.00%)**	**1/512 (0.20%)**
Atrial fibrillation † 1		
# participants affected / at risk	**0/493 (0.00%)**	**1/512 (0.20%)**
Cardiac failure † 1		
# participants affected / at risk	**0/493 (0.00%)**	**1/512 (0.20%)**
Coronary artery disease † 1		
# participants affected / at risk	**0/493 (0.00%)**	**1/512 (0.20%)**

Myocardial infarction † 1		
# participants affected / at risk	**0/493 (0.00%)**	**3/512 (0.59%)**
Ear and labyrinth disorders		
Vertigo † 1		
# participants affected / at risk	**0/493 (0.00%)**	**1/512 (0.20%)**
Endocrine disorders		
Thyroid cyst † 1		
# participants affected / at risk	**0/493 (0.00%)**	**1/512 (0.20%)**
Gastrointestinal disorders		
Abdominal pain upper † 1		
# participants affected / at risk	**0/493 (0.00%)**	**1/512 (0.20%)**
Enterovesical fistula † 1		
# participants affected / at risk	**1/493 (0.20%)**	**0/512 (0.00%)**
Oesophagitis † 1		
# participants affected / at risk	**0/493 (0.00%)**	**1/512 (0.20%)**
General disorders		
Chest pain † 1		
# participants affected / at risk	**0/493 (0.00%)**	**1/512 (0.20%)**
Hepatobiliary disorders		
Cholecystitis acute † 1		
# participants affected / at risk	**0/493 (0.00%)**	**1/512 (0.20%)**
Infections and infestations		
Appendicitis † 1		
# participants affected / at risk	**0/493 (0.00%)**	**1/512 (0.20%)**
Cystitis † 1		
# participants affected / at risk	**1/493 (0.20%)**	**0/512 (0.00%)**
Diverticulitis † 1		
# participants affected / at risk	**1/493 (0.20%)**	**0/512 (0.00%)**
Erysipelas † 1		
# participants affected / at risk	**1/493 (0.20%)**	**0/512 (0.00%)**
Peritonsillar abscess † 1		
# participants affected / at risk	**0/493 (0.00%)**	**1/512 (0.20%)**
Pneumonia † 1		
# participants affected / at risk	**0/493 (0.00%)**	**1/512 (0.20%)**
Pyelonephritis † 1		
# participants affected / at risk	**1/493 (0.20%)**	**0/512 (0.00%)**
Injury, poisoning and procedural complications		
Ligament rupture † 1		
# participants affected / at risk	**0/493 (0.00%)**	**1/512 (0.20%)**
Musculoskeletal and connective tissue disorders		
Haemarthrosis † 1		
# participants affected / at risk	**0/493 (0.00%)**	**1/512 (0.20%)**
Intervertebral disc displacement † 1		

# participants affected / at risk	0/493 (0.00%)	1/512 (0.20%)
Osteoarthritis † 1		
# participants affected / at risk	1/493 (0.20%)	0/512 (0.00%)
Pain in extremity † 1		
# participants affected / at risk	0/493 (0.00%)	1/512 (0.20%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Breast cancer metastatic † 1		
# participants affected / at risk	0/493 (0.00%)	1/512 (0.20%)
Nervous system disorders		
Cerebrovascular accident † 1		
# participants affected / at risk	0/493 (0.00%)	1/512 (0.20%)
Transient ischaemic attack † 1		
# participants affected / at risk	0/493 (0.00%)	1/512 (0.20%)
Reproductive system and breast disorders		
Breast dysplasia † 1		
# participants affected / at risk	0/493 (0.00%)	1/512 (0.20%)
Surgical and medical procedures		
Cyst removal † 1		
# participants affected / at risk	1/493 (0.20%)	0/512 (0.00%)
Dupuytren's contracture operation † 1		
# participants affected / at risk	1/493 (0.20%)	0/512 (0.00%)
Vascular disorders		
Arterial stenosis † 1		
# participants affected / at risk	1/493 (0.20%)	0/512 (0.00%)
Arteriosclerosis † 1		
# participants affected / at risk	0/493 (0.00%)	1/512 (0.20%)

† 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 patients who received 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	10% terbinafine hydrogen chloride (72.6 mg/ml nail lacquer). Patients applied one layer of the study medication once daily for 48 weeks, preferably at bedtime, to all affected toenails and allowed to dry.
Amorolfine	5% amorolfine nail lacquer. Patients applied study medication twice weekly for 48 weeks to all affected toenails.

Other Adverse Events

	Terbinafine	Amorolfine
Total, other (not including serious) adverse events		
# participants affected / at risk	**186/493 (37.73%)**	**168/512 (32.81%)**
Infections and infestations		
Influenza † 1		
# participants affected / at risk	**25/493 (5.07%)**	**15/512 (2.93%)**
Nasopharyngitis † 1		
# participants affected / at risk	**69/493 (14.00%)**	**65/512 (12.70%)**
Tinea pedis † 1		
# participants affected / at risk	**29/493 (5.88%)**	**33/512 (6.45%)**
Musculoskeletal and connective tissue disorders		
Back pain † 1		
# participants affected / at risk	**26/493 (5.27%)**	**29/512 (5.66%)**
Nervous system disorders		
Headache † 1		
# participants affected / at risk	**98/493 (19.88%)**	**70/512 (13.67%)**

† 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:	External Affairs, Novartis
ClinicalTrials.gov Identifier:	NCT00459537 History of Changes
Other Study ID Numbers:	**CSFO327N2303**
Study First Received:	April 10, 2007
Results First Received:	January 19, 2011
Last Updated:	May 3, 2011
Health Authority:	Finland: Finnish Medicines Agency France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis) Germany: Federal Institute for Drugs and Medical Devices Hungary: Országos Gyógyszerészeti Intézet Iceland: Icelandic Medicines Control Agency Norway: Norwegian Medicines Agency Poland: Central Register of Clinical Trials Russia: Ministry of Health of the Russian Federation Spain: Ministry of Health Turkey: T.C. Sağlık Bakanlığı