ClinicalTrials.gov

A service of the U.S. National Institutes of Health

Try our beta test site

Trial record **1 of 1** for: FPP4-DE-401

Previous Study | Return to List | Next Study

A Comparative Study of the Efficacy of Penciclovir 10mg/g (1%) Cream in Preventing the Appearance of Classical Lesion in Recurrent Cold Sore Sufferers

This study has been completed.

Sponsor:
Novartis

Information provided by (Responsible Party):
Novartis

ClinicalTrials.gov Identifier:
NCT00820534

First received: January 9, 2009
Last updated: April 18, 2012
Last verified: December 2010
History of Changes

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

Results First Received: November 12, 2010

Study Type:	Interventional
Study Design:	Allocation: Randomized; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Prevention
Condition:	Cold Sore
Interventions:	Drug: Penciclovir 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
Study start : 30 dec 2008 Study end : 16 Nov 2009 Hospital out patient clinic

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
Cold Sore confirmed by local temperature measurement

Reporting Groups

	Description
Penciclovir	Penciclovir 10mg/g (1%) cream every 2 hours during waking hours for 96 hours
Placebo	Placebo cream every 2 hours during waking hours for 96 hours

Participant Flow: Overall Study

	Penciclovir	Placebo
STARTED	**64**	**62**
COMPLETED	**64**	**62**
NOT COMPLETED	**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
Penciclovir	Penciclovir 10mg/g (1%) cream every 2 hours during waking hours for 96 hours
Placebo	Placebo cream every 2 hours during waking hours for 96 hours
Total	Total of all reporting groups

Baseline Measures

	Penciclovir	Placebo	Total
Overall Participants Analyzed [Units: Participants]	**64**	**62**	**126**
Age [Units: Participants]			
<=18 years	**0**	**0**	**0**
Between 18 and 65 years	**63**	**62**	**125**
>=65 years	**1**	**0**	**1**
Age [Units: Years] Mean (Standard Deviation)	**31.4 (11.3)**	**31.8 (9.3)**	**31.6 (10.4)**
Gender [Units: Participants]			
Female	**43**	**40**	**83**
Male	**21**	**22**	**43**
Region of Enrollment [Units: Participants]			

United Kingdom	**64**	**62**	**126**

Outcome Measures

Hide All Outcome Measures

1. Primary: Clinical Assessment Performed by the Investigator and Skin Temperature at the Cold Sore. [Time Frame: 72 hours]

Measure Type	Primary
Measure Title	Clinical Assessment Performed by the Investigator and Skin Temperature at the Cold Sore.
Measure Description	Number of participants where the classical cold sore lesion was prevented at 72 hours after first treatment application.Lesion defined as having been prevented if clinical assessment is prodrome, macule or healed and skin temperature of the cold sore is negative (temperature difference of less than 0.5°C between initial site of cold sore and opposite side).
Time Frame	72 hours

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
Penciclovir	Penciclovir 10mg/g (1%) cream every 2 hours during waking hours for 96 hours
Placebo	Placebo cream every 2 hours during waking hours for 96 hours

Measured Values

	Penciclovir	**Placebo**
Participants Analyzed [Units: Participants]	**64**	**62**

Clinical Assessment Performed by the Investigator and Skin Temperature at the Cold Sore. [Units: Participants]	**39**	**32**

No statistical analysis provided for Clinical Assessment Performed by the Investigator and Skin Temperature at the Cold Sore.

2. Secondary: Size of the Cold Sore [Time Frame: 72 hours]

Measure Type	Secondary
Measure Title	Size of the Cold Sore
Measure Description	The size of the cold sore was measured as follows : a standardized photograph was taken before treatment and compared to a photograph taken 72 hours after the first treatment application. The difference was calculated for each participant within each treatment arm.
Time Frame	72 hours

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
Penciclovir	Penciclovir 10mg/g (1%) cream every 2 hours during waking hours for 96 hours
Placebo	Placebo cream every 2 hours during waking hours for 96 hours

Measured Values

	Penciclovir	**Placebo**
Participants Analyzed [Units: Participants]	**64**	**62**

Size of the Cold Sore [Units: Square mm] Mean (95% Confidence Interval)	**31.7** **(20.8 to 42.6)**	**32.7** **(21.3 to 44.2)**

No statistical analysis provided for Size of the Cold Sore

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Reporting Groups

	Description
Penciclovir	Penciclovir 10mg/g (1%) cream every 2 hours during waking hours for 96 hours
Placebo	Placebo cream every 2 hours during waking hours for 96 hours

Serious Adverse Events

	Penciclovir	**Placebo**
Total, Serious Adverse Events		
# participants affected / at risk	**0/64 (0.00%)**	**0/62 (0.00%)**

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	2%

Reporting Groups

	Description
Penciclovir	Penciclovir 10mg/g (1%) cream every 2 hours during waking hours for 96 hours
Placebo	Placebo cream every 2 hours during waking hours for 96 hours

Other Adverse Events

	Penciclovir	Placebo
Total, Other (not including serious) Adverse Events		
# participants affected / at risk	**0/64 (0.00%)**	**0/62 (0.00%)**

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 **NOT** 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.

Results Point of Contact:

Name/Title: Head of Clinical Research
Organization: Novartis Consumer Health
phone: +4122363311

Responsible Party:	Novartis
ClinicalTrials.gov Identifier:	NCT00820534 History of Changes
Other Study ID Numbers:	**FPP4-DE-401**
Study First Received:	January 9, 2009
Results First Received:	November 12, 2010
Last Updated:	April 18, 2012