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Trial record **1 of 1** for: 075-A-301

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Efficacy and Safety of a Sore Throat Lozenge Containing Lidocaine and Cetylpyridinium Chloride in Patients With Sore Throat Due to a Common Cold.

This study has been completed.

Sponsor:
Novartis

Information provided by (Responsible Party):
Novartis

ClinicalTrials.gov Identifier:
NCT01265446

First received: December 20, 2010
Last updated: April 17, 2013
Last verified: April 2013
History of Changes

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

Results First Received: March 29, 2012

Study Type:	Interventional
Study Design:	Allocation: Randomized; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Condition:	Sore Throat Due to a Common Cold
Interventions:	Drug: Lidocaine 8mg + CPC 2mg Drug: Lidocaine 1mg + CPC 2mg

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
14 Dec 2010 to 5 Apr 2011

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
Lidocaine 8mg +CPC 2mg	one single dose
Lidocaine 1mg + CPC 2mg	one single dose

Participant Flow: Overall Study

	Lidocaine 8mg +CPC 2mg	Lidocaine 1mg + CPC 2mg
STARTED	**125**	**125**
COMPLETED	**124**	**125**
NOT COMPLETED	**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
Lidocaine 8mg +CPC 2mg	one single dose
Lidocaine 1mg + CPC 2mg	one single dose
Total	Total of all reporting groups

Baseline Measures

	Lidocaine 8mg +CPC 2mg	Lidocaine 1mg + CPC 2mg	Total
Overall Participants Analyzed [Units: Participants]	**125**	**125**	**250**
Age [Units: Participants]			
<=18 years	**0**	**0**	**0**
Between 18 and 65 years	**125**	**125**	**250**
>=65 years	**0**	**0**	**0**
Age [Units: Years] Mean (Standard Deviation)	**32.1 (12.6)**	**31.6 (11.6)**	**31.9 (12.1)**
Gender [Units: Participants]			
Female	**67**	**67**	**134**
Male	**58**	**58**	**116**
Region of Enrollment [Units: Participants]			

Germany	**125**	**125**	**250**

Outcome Measures

Hide All Outcome Measures

1. Primary: Change From Baseline Sore Throat Pain Intensity [Time Frame: Baseline and 2 hours post-dose]

Measure Type	Primary
Measure Title	Change From Baseline Sore Throat Pain Intensity
Measure Description	100 milimeter (mm) visual acuity score (left=no pain=0mm, right=worst possible pain=100mm)
Time Frame	Baseline and 2 hours post-dose

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

Reporting Groups

	Description
Lidocaine 8mg +CPC 2mg	one single dose
Lidocaine 1mg + CPC 2mg	one single dose

Measured Values

	Lidocaine 8mg +CPC 2mg	**Lidocaine 1mg + CPC 2mg**
Participants Analyzed [Units: Participants]	**125**	**125**
	-27.4 **(-31.0 to -23.8)**	**-26.9** **(-30.5 to -23.3)**

Change From Baseline Sore Throat Pain Intensity [Units: Mm] Mean (95% Confidence Interval)		

No statistical analysis provided for Change From Baseline Sore Throat Pain Intensity

2. Secondary: Change From Baseline Sore Throat Pain Intensity up to 240 mn Post-dose [Time Frame: Baseline and 240 mn post-dose]

Measure Type	Secondary
Measure Title	Change From Baseline Sore Throat Pain Intensity up to 240 mn Post-dose
Measure Description	100 milimeter (mm) visual acuity score (left=no pain=0mm, right=worst possible pain=100mm). It measures the highest pain level felt by the patient.
Time Frame	Baseline and 240 mn post-dose

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

Reporting Groups

	Description
Lidocaine 8mg +CPC 2mg	one single dose
Lidocaine 1mg + CPC 2mg	one single dose

Measured Values

	Lidocaine 8mg +CPC 2mg	**Lidocaine 1mg + CPC 2mg**
Participants Analyzed [Units: Participants]	**125**	**125**

Change From Baseline Sore Throat Pain Intensity up to 240 mn Post-dose [Units: Mm] Mean (95% Confidence Interval)	**-25.5** **(-29.8 to -21.2)**	**-29.1** **(-33.1 to -25.1)**

No statistical analysis provided for Change From Baseline Sore Throat Pain Intensity up to 240 mn Post-dose

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	14 Dec 2010 to 5 Apr 2011
Additional Description	No text entered.

Reporting Groups

	Description
Lidocaine 8mg +CPC 2mg	one single dose
Lidocaine 1mg + CPC 2mg	one single dose

Serious Adverse Events

	Lidocaine 8mg +CPC 2mg	Lidocaine 1mg + CPC 2mg
Total, Serious Adverse Events		
# participants affected / at risk	**1/125 (0.80%)**	**0/125 (0.00%)**
Injury, poisoning and procedural complications		
Tendon rupture [1]		
# participants affected / at risk	**1/125 (0.80%)**	**0/125 (0.00%)**
# events	**1**	**0**

1 Term from vocabulary, MedDRA

Other Adverse Events

Hide Other Adverse Events

Time Frame	14 Dec 2010 to 5 Apr 2011
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	0%

Reporting Groups

	Description
Lidocaine 8mg +CPC 2mg	one single dose
Lidocaine 1mg + CPC 2mg	one single dose

Other Adverse Events

	Lidocaine 8mg +CPC 2mg	Lidocaine 1mg + CPC 2mg
Total, Other (not including serious) Adverse Events		
# participants affected / at risk	**10/125 (8.00%)**	**9/125 (7.20%)**
Nervous system disorders		
Headache [1]		
# participants affected / at risk	**7/125 (5.60%)**	**6/125 (4.80%)**
# events	**7**	**6**
dizziness [1]		
# participants affected / at risk	**0/125 (0.00%)**	**1/125 (0.80%)**
# events	**0**	**1**
hyperaesthesia [1]		
# participants affected / at risk	**1/125 (0.80%)**	**0/125 (0.00%)**

# events	**1**	**0**
vertigo [1]		
# participants affected / at risk	**1/125 (0.80%)**	**0/125 (0.00%)**
# events	**1**	**0**
Respiratory, thoracic and mediastinal disorders		
Throat Irritation [1]		
# participants affected / at risk	**1/125 (0.80%)**	**1/125 (0.80%)**
# events	**1**	**1**
Asthma [1]		
# participants affected / at risk	**0/125 (0.00%)**	**1/125 (0.80%)**
# events	**0**	**1**
Stridor [1]		
# participants affected / at risk	**1/125 (0.80%)**	**0/125 (0.00%)**
# events	**1**	**0**
Skin and subcutaneous tissue disorders		
Rash [1]		
# participants affected / at risk	**1/125 (0.80%)**	**0/125 (0.00%)**
# events	**1**	**0**

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: Preliminary agreement between Novartis Consumer Health and the investigator

Results Point of Contact:

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Responsible Party:	Novartis
ClinicalTrials.gov Identifier:	NCT01265446 History of Changes
Other Study ID Numbers:	**075-A-301**
	2010-021653-39 (EudraCT Number)
Study First Received:	December 20, 2010
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