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Trial record **1 of 1** for: VOPO-P-307

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Evaluate the Efficacy and Safety of Diclofenac Diethylamine 2.32% Gel Applied Twice or Three Times Daily in Patients With Acute Ankle Sprain

This study has been completed.

Sponsor:
Novartis

Information provided by (Responsible Party):
Novartis

ClinicalTrials.gov Identifier:
NCT00955513

First received: August 7, 2009
Last updated: April 18, 2012
Last verified: January 2011
History of Changes

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

Results First Received: December 1, 2010

Study Type:	Interventional
Study Design:	Allocation: Randomized; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Condition:	Grade I/II Ankle Sprain
Interventions:	Drug: diclofenac diethylamine gel 2.32% 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
6 centers in Germany. Recruitment commenced in July 2009 and completed in December 2009.

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
Diclofenac Diethylamine Gel 2.32% Gel. Applied 2 Times a Day	drug
Diclofenac Diethylamine Gel 2.32% Gel. Applied 3 Times a Day	drug
Placebo. Applied 3 Times a Day.	placebo

Participant Flow: Overall Study

	Diclofenac Diethylamine Gel 2.32% Gel. Applied 2 Times a Day	Diclofenac Diethylamine Gel 2.32% Gel. Applied 3 Times a Day	Placebo. Applied 3 Times a Day.
STARTED	**80**	**80**	**82**
COMPLETED	**79**	**78**	**79**
NOT COMPLETED	**1**	**2**	**3**

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
Diclofenac Diethylamine Gel 2.32% Gel. Applied 2 Times a Day	drug
Diclofenac Diethylamine Gel 2.32% Gel. Applied 3 Times a Day	drug
Placebo. Applied 3 Times a Day.	placebo
Total	Total of all reporting groups

Baseline Measures

	Diclofenac Diethylamine Gel 2.32% Gel. Applied 2 Times a Day	**Diclofenac Diethylamine Gel 2.32% Gel. Applied 3 Times a Day**	**Placebo. Applied 3 Times a Day.**	**Total**
Overall Participants Analyzed [Units: Participants]	**80**	**80**	**82**	**242**
Age [Units: Participants]				
<=18 years	**0**	**0**	**0**	**0**
Between 18 and 65 years	**80**	**77**	**81**	**238**
>=65 years	**0**	**3**	**1**	**4**
Age [Units: Years] Mean (Standard Deviation)	**30.9 (11.4)**	**32.2 (13.7)**	**34.0 (12.9)**	**32.4 (12.7)**

Gender [Units: Participants]				
Female	**31**	**31**	**28**	**90**
Male	**49**	**49**	**54**	**152**
Region of Enrollment [Units: Participants]				
Germany	**80**	**80**	**82**	**242**

Outcome Measures

1. Primary: Measure: Pain on Movement on Day 5 (Change From Baseline). [Time Frame: baseline and day 5]

Hide Outcome Measure 1

Measure Type	Primary
Measure Title	Measure: Pain on Movement on Day 5 (Change From Baseline).
Measure Description	Visual analog scale (0 to 100 mm) A greater change from baseline equates to a better outcome.
Time Frame	baseline and day 5

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
Diclofenac Diethylamine Gel 2.32% Gel. Applied 2 Times a Day	drug
Diclofenac Diethylamine Gel 2.32% Gel. Applied 3 Times a Day	drug

Placebo. Applied 3 Times a Day.	placebo

Measured Values

	Diclofenac Diethylamine Gel 2.32% Gel. Applied 2 Times a Day	Diclofenac Diethylamine Gel 2.32% Gel. Applied 3 Times a Day	Placebo. Applied 3 Times a Day.
Participants Analyzed [Units: Participants]	**80**	**80**	**82**
Measure: Pain on Movement on Day 5 (Change From Baseline). [Units: Mm] Mean (Standard Deviation)	**49.1 (19.3)**	**49.7 (21.5)**	**25.4 (14.8)**

No statistical analysis provided for Measure: Pain on Movement on Day 5 (Change From Baseline).

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
Diclofenac Diethylamine Gel 2.32% Gel. Applied 2 Times a Day	drug
Diclofenac Diethylamine Gel 2.32% Gel. Applied 3 Times a Day	drug
Placebo. Applied 3 Times a Day.	placebo

Serious Adverse Events

	Diclofenac Diethylamine Gel 2.32% Gel. Applied 2 Times a Day	Diclofenac Diethylamine Gel 2.32% Gel. Applied 3 Times a Day	Placebo. Applied 3 Times a Day.
Total, Serious Adverse Events			
# participants affected / at risk	**0/80 (0.00%)**	**0/80 (0.00%)**	**0/82 (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	0%

Reporting Groups

	Description
Diclofenac Diethylamine Gel 2.32% Gel. Applied 2 Times a Day	drug
Diclofenac Diethylamine Gel 2.32% Gel. Applied 3 Times a Day	drug
Placebo. Applied 3 Times a Day.	placebo

Other Adverse Events

	Diclofenac Diethylamine Gel 2.32% Gel. Applied 2 Times a Day	Diclofenac Diethylamine Gel 2.32% Gel. Applied 3 Times a Day	Placebo. Applied 3 Times a Day.
Total, Other (not including serious) Adverse Events			

# participants affected / at risk	**0/80 (0.00%)**	**1/80 (1.25%)**	**1/82 (1.22%)**
Nervous system disorders			
Headache † 1			
# participants affected / at risk	**0/80 (0.00%)**	**1/80 (1.25%)**	**1/82 (1.22%)**
# events	**0**	**1**	**1**

† 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 **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: Clinical Project Leader Pain category
Organization: Novartis Consumer Health
phone: +41223635528

Responsible Party:	Novartis
ClinicalTrials.gov Identifier:	NCT00955513 History of Changes
Other Study ID Numbers:	**VOPO-P-307**
Study First Received:	August 7, 2009
Results First Received:	December 1, 2010
Last Updated:	April 18, 2012