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Trial record **1 of 1** for: VOSG-P-319

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Efficacy and Safety of Diclofenac Sodium Topical Gel 1% Applied Four Times Daily in Subjects With Acute Blunt Trauma Injuries

This study has been completed.

Sponsor:
Novartis

Information provided by (Responsible Party):
Novartis

ClinicalTrials.gov Identifier:
NCT01272947

First received: January 7, 2011
Last updated: December 6, 2012
Last verified: December 2012
History of Changes

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

Results First Received: July 17, 2012

Study Type:	Interventional
Study Design:	Allocation: Randomized; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Condition:	Acute Blunt Soft Tissue Injuries/Contusions
Interventions:	Drug: Diclofenac sodium Other: 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
Diclofenac Sodium Topical Gel 1%	No text entered.
Placebo	No text entered.

Participant Flow: Overall Study

	Diclofenac Sodium Topical Gel 1%	Placebo
STARTED	**104**	**100**
COMPLETED	**102**	**98**
NOT COMPLETED	**2**	**2**
Abnormal Laboratory Value	**2**	**2**

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 Sodium Topical Gel 1%	No text entered.
Placebo	No text entered.
Total	Total of all reporting groups

Baseline Measures

	Diclofenac Sodium Topical Gel 1%	Placebo	Total
Overall Participants Analyzed [Units: Participants]	**104**	**100**	**204**
Age [Units: Years] Mean (Standard Deviation)			
Unit : years	**29.4 (9.6)**	**31.4 (12.1)**	**30.4 (10.9)**
Gender [Units: Participants]			
Female	**55**	**48**	**103**
Male	**49**	**52**	**101**
Region of Enrollment [Units: Participants]			
Germany	**104**	**100**	**204**

Outcome Measures

Hide All Outcome Measures

1. Primary: Pain on Movement [Time Frame: VAS Score at 24 hours]

Measure Type	Primary
Measure Title	Pain on Movement
Measure Description	Visual analog scale (VAS) assessed on a 100 mm scale with anchors at 0= "No pain" and 100= "Extreme pain"
Time Frame	VAS Score at 24 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
Diclofenac Sodium Topical Gel 1%	No text entered.
Placebo	No text entered.

Measured Values

	Diclofenac Sodium Topical Gel 1%	**Placebo**
Participants Analyzed [Units: Participants]	**104**	**100**
Pain on Movement [Units: Mm] Mean (Standard Deviation)	**33.1 (21.4)**	**65.4 (16.9)**

No statistical analysis provided for Pain on Movement

2. Secondary: Onset of Pain Relief [Time Frame: From randomization to end of day 1]

Measure Type	Secondary
Measure Title	Onset of Pain Relief
Measure Description	Onset of perceptible pain relief.
Time Frame	From randomization to end of day 1

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 Sodium Topical Gel 1%	No text entered.
Placebo	No text entered.

Measured Values

	Diclofenac Sodium Topical Gel 1%	**Placebo**
Participants Analyzed [Units: Participants]	**104**	**100**
Onset of Pain Relief [Units: Hours] Median (Inter-Quartile Range)	**2** **(1 to 4)**	**NA** [1] **(4.9 to N/A)**

[1] The median time was not reached in the placebo group.

No statistical analysis provided for Onset of Pain Relief

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
Diclofenac Sodium Topical Gel 1%	No text entered.
Placebo	No text entered.

Serious Adverse Events

	Diclofenac Sodium Topical Gel 1%	**Placebo**
Total, Serious Adverse Events		
# participants affected / at risk	**0/104 (0.00%)**	**0/100 (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	1%

Reporting Groups

	Description
Diclofenac Sodium Topical Gel 1%	No text entered.
Placebo	No text entered.

Other Adverse Events

	Diclofenac Sodium Topical Gel 1%	Placebo
Total, Other (not including serious) Adverse Events		
# participants affected / at risk	**2/104 (1.92%)**	**4/100 (4.00%)**
Infections and infestations		
Infections and Infestations † 1		
# participants affected / at risk	**2/104 (1.92%)**	**3/100 (3.00%)**
# events	**2**	**3**
Musculoskeletal and connective tissue disorders		
Musculoskeletal and connective tissue disorders † 1		
# participants affected / at risk	**0/104 (0.00%)**	**1/100 (1.00%)**
# events	**0**	**1**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDra 10.0

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 Principal Investigator

Results Point of Contact:

Name/Title: Clinical Project Leader
Organization: Novartis Consumer Health S.A.
phone: +41 22 3635528

Responsible Party: Novartis
ClinicalTrials.gov Identifier: NCT01272947 History of Changes

Other Study ID Numbers:	**VOSG-P-319**
Study First Received:	January 7, 2011
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