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Trial record **1 of 1** for: 862-P-201

Previous Study | Return to List | Next Study

Efficacy and Safety of Diclofenac 1.16% Gel in Subjects With Acute Neck Pain

This study has been completed.

Sponsor:
Novartis

Information provided by (Responsible Party):
Novartis

ClinicalTrials.gov Identifier:
NCT01335724

First received: April 13, 2011
Last updated: June 14, 2012
Last verified: June 2012
History of Changes

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

Results First Received: May 11, 2012

Study Type:	Interventional
Study Design:	Allocation: Randomized; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
Condition:	Neck Pain
Interventions:	Drug: Diclofenac diethylamine 1.16% gel Drug: Placebo gel

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 Diethylamine 1.16% Gel	No text entered.
Placebo Gel	No text entered.

Participant Flow: Overall Study

	Diclofenac Diethylamine 1.16% Gel	Placebo Gel
STARTED	**36**	**36**
COMPLETED	**36**	**36**
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
Diclofenac Diethylamine 1.16% Gel	No text entered.
Placebo Gel	No text entered.
Total	Total of all reporting groups

Baseline Measures

	Diclofenac Diethylamine 1.16% Gel	Placebo Gel	Total
Overall Participants Analyzed [Units: Participants]	**36**	**36**	**72**
Age [Units: Participants]			
<=18 years	**0**	**0**	**0**
Between 18 and 65 years	**36**	**34**	**70**
>=65 years	**0**	**2**	**2**
Age [Units: Years] Mean (Standard Deviation)	**29.8 (10.5)**	**37.8 (15.2)**	**33.8 (13.6)**
Gender [Units: Participants]			
Female	**19**	**14**	**33**
Male	**17**	**22**	**39**
Region of Enrollment [Units: Participants]			
Germany	**36**	**36**	**72**

Outcome Measures

Hide All Outcome Measures

1. Primary: Pain on Movement [Time Frame: 48 h]

Measure Type	Primary
Measure Title	Pain on Movement
Measure Description	Pain on movement on a 100 mm visual analog scale. Minimum score =0 mm "no pain". Maximum score =100 mm "extreme pain".
Time Frame	48 h

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 1.16% Gel	No text entered.
Placebo Gel	No text entered.

Measured Values

	Diclofenac Diethylamine 1.16% Gel	**Placebo Gel**
Participants Analyzed [Units: Participants]	**36**	**36**
Pain on Movement [Units: Mm] Mean (Standard Deviation)	**19.5 (12.9)**	**56.9 (16.1)**

No statistical analysis provided for Pain on Movement

2. Secondary: Pain at Rest [Time Frame: 96h]

Measure Type	Secondary
Measure Title	Pain at Rest
Measure Description	Pain at Rest on a 100 mm visual analog scale. Minimum score =0 mm "no pain". Maximum score =100 mm "extreme pain".
Time Frame	96h

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 1.16% Gel	No text entered.
Placebo Gel	No text entered.

Measured Values

	Diclofenac Diethylamine 1.16% Gel	**Placebo Gel**
Participants Analyzed [Units: Participants]	**36**	**36**
Pain at Rest [Units: Mm] Mean (Standard Deviation)	**1.2 (2.9)**	**19.2 (11.9)**

No statistical analysis provided for Pain at Rest

3. Secondary: Neck Disability Index [Time Frame: 96h]

Measure Type	Secondary
Measure Title	Neck Disability Index
Measure Description	Neck Disability Index total score. Minimum = 0 "Best". Maximum = 50 "Worst"
Time Frame	96h

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 1.16% Gel	No text entered.
Placebo Gel	No text entered.

Measured Values

	Diclofenac Diethylamine 1.16% Gel	**Placebo Gel**
Participants Analyzed [Units: Participants]	**36**	**36**
Neck Disability Index [Units: Total Score] Mean (Standard Deviation)	**2.8 (3.0)**	**14.6 (6.8)**

No statistical analysis provided for Neck Disability Index

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
Diclofenac Diethylamine 1.16% Gel	No text entered.
Placebo Gel	No text entered.

Serious Adverse Events

	Diclofenac Diethylamine 1.16% Gel	Placebo Gel
Total, Serious Adverse Events		
# participants affected / at risk	**0/36 (0.00%)**	**0/36 (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	2.00%

Reporting Groups

	Description
Diclofenac Diethylamine 1.16% Gel	No text entered.
Placebo Gel	No text entered.

Other Adverse Events

	Diclofenac Diethylamine 1.16% Gel	**Placebo Gel**
Total, Other (not including serious) Adverse Events		
# participants affected / at risk	**0/36 (0.00%)**	**1/36 (2.78%)**
Nervous system disorders		
Headache † 1		
# participants affected / at risk	**0/36 (0.00%)**	**1/36 (2.78%)**
# events	**0**	**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** 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:

Name/Title: Clinical project Leader
Organization: Novartis Consumer Health
phone: +41223635528

Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Predel HG, Giannetti B, Pabst H, Schaefer A, Hug AM, Burnett I. Efficacy and safety of diclofenac diethylamine 1.16% gel in acute neck pain: a randomized, double-blind, placebo-controlled study. BMC Musculoskelet Disord. 2013 Aug 21;14:250. doi: 10.1186/1471-2474-14-250.

Responsible Party: Novartis
ClinicalTrials.gov Identifier: NCT01335724 History of Changes
Other Study ID Numbers: **862-P-201**

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