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

Trial record **1 of 1** for: C-09-055

Previous Study | Return to List | Next Study

Confirmatory Study Nepafenac 0.3%

This study has been completed.

Sponsor:
Alcon Research

Information provided by (Responsible Party):
Alcon Research

ClinicalTrials.gov Identifier:
NCT01109173

First received: April 21, 2010
Last updated: November 29, 2012
Last verified: November 2012
History of Changes

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

Results First Received: November 1, 2012

Study Type:	Interventional
Study Design:	Allocation: Randomized; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Condition:	Cataract
Interventions:	Drug: Nepafenac Ophthalmic Suspension, 0.3% Drug: Nepafenac Ophthalmic Suspension, 0.1% Other: Nepafenac Ophthalmic Suspension 0.3% Vehicle Other: NEVANAC Vehicle

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
Patients were randomized from 65 sites in 5 countries: US (49), Hungary (6), Italy (4), Sweden (4), and Switzerland (2).

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
Of the 2120 enrolled participants, 78 withdrew before the start of dosing. Baseline characteristics are presented on all randomized patients with at least 1 postoperative assessment (ITT): 2022.

Reporting Groups

	Description
Nepafenac 0.3%	Nepafenac Ophthalmic Suspension, 0.3%, one drop in affected eye once daily for 16 days, beginning one day prior to surgery, continuing on the day of surgery, and for 14 days following surgery. An additional dose was administered between 30-120 minutes prior to surgery.
NEVANAC	Nepafenac Ophthalmic Suspension, 0.1%, one drop in affected eye three times daily, beginning one day prior to surgery, continuing on the day of surgery, and for 14 days following surgery.
Nepafenac Vehicle 0.3%	Nepafenac Ophthalmic Suspension 0.3% Vehicle, one drop in affected eye once daily for 16 days, beginning one

	day prior to surgery, continuing on the day of surgery, and for 14 days following surgery. An additional dose was administered between 30-120 minutes prior to surgery.
NEVANAC Vehicle	Nepafenac 0.1% vehicle, one drop in affected eye three times daily, beginning one day prior to surgery, continuing on the day of surgery, and for 14 days following surgery.

Participant Flow: Overall Study

	Nepafenac 0.3%	NEVANAC	Nepafenac Vehicle 0.3%	NEVANAC Vehicle
STARTED	851	845	211	213
COMPLETED	763	759	110	120
NOT COMPLETED	88	86	101	93
Adverse Event	15	17	9	6
Lost to Follow-up	0	1	0	0
Patient Decision Unrelated to Advrs Evnt	5	0	2	0
Noncompliance	0	1	0	0
Treatment Failure	25	32	69	64
Protocol Violation	4	5	1	2
Patient Did Not Use Study Medication	34	26	11	7
Not Specifiied	5	4	9	14

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
Nepafenac 0.3%	Nepafenac Ophthalmic Suspension, 0.3%, one drop in affected eye once daily for 16 days, beginning one day prior to surgery, continuing on the day of surgery, and for 14 days following surgery. An additional dose was administered between 30-120 minutes prior to surgery.
NEVANAC	Nepafenac Ophthalmic Suspension, 0.1%, one drop in affected eye three times daily, beginning one day prior to surgery, continuing on the day of surgery, and for 14 days following surgery.
Nepafenac Vehicle 0.3%	Nepafenac Ophthalmic Suspension 0.3% Vehicle, one drop in affected eye once daily for 16 days, beginning one day prior to surgery, continuing on the day of surgery, and for 14 days following surgery. An additional dose was administered between 30-120 minutes prior to surgery.
NEVANAC Vehicle	Nepafenac 0.1% vehicle, one drop in affected eye three times daily, beginning one day prior to surgery, continuing on the day of surgery, and for 14 days following surgery.
Total	Total of all reporting groups

Baseline Measures

	Nepafenac 0.3%	NEVANAC	Nepafenac Vehicle 0.3%	NEVANAC Vehicle	Total
Number of Participants [units: participants]	807	813	197	205	2022
Age [units: years]	68.7 (9.08)	68.8 (9.31)	69.8 (9.31)	68.9 (9.37)	68.9 (9.22)

Mean (Standard Deviation)					
Gender [units: participants]					
Female	**465**	**458**	**118**	**115**	**1156**
Male	**342**	**355**	**79**	**90**	**866**

Outcome Measures

Hide All Outcome Measures

1. Primary: Percentage of Patients Cured at Day 14 [Time Frame: Day 14]

Measure Type	Primary
Measure Title	Percentage of Patients Cured at Day 14
Measure Description	Ocular inflammation was assessed by the investigator during slit lamp examination. Aqueous cells were scored on a 5-unit scale from 0 (none) to 4 (> 30 cells), and aqueous flare (protein escaping from dilated vessels) was scored on a 4-unit scale from 0 (no visible flare when compared with the normal eye) to 3 (severe – very dense flare). To be considered cured, the patient must have had a score of 0 for both cells and flare.
Time Frame	Day 14
Safety Issue	No

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.
All randomized patients with at least one postoperative assessment (ITT), last observation carried forward.

Reporting Groups

	Description
Nepafenac 0.3%	Nepafenac Ophthalmic Suspension, 0.3%, one drop in affected eye once daily for 16 days, beginning one day prior to surgery, continuing on the day of surgery, and for 14 days following surgery. An additional dose was administered between 30-120 minutes prior to surgery.
NEVANAC	Nepafenac Ophthalmic Suspension, 0.1%, one drop in affected eye three times daily, beginning one day prior to surgery, continuing on the day of surgery, and for 14 days following surgery.
Nepafenac Vehicle 0.3%	Nepafenac Ophthalmic Suspension 0.3% Vehicle, one drop in affected eye once daily for 16 days, beginning one day prior to surgery, continuing on the day of surgery, and for 14 days following surgery. An additional dose was administered between 30-120 minutes prior to surgery.
NEVANAC Vehicle	Nepafenac 0.1% vehicle, one drop in affected eye three times daily, beginning one day prior to surgery, continuing on the day of surgery, and for 14 days following surgery.

Measured Values

	Nepafenac 0.3%	**NEVANAC**	**Nepafenac Vehicle 0.3%**	**NEVANAC Vehicle**
Number of Participants Analyzed [units: participants]	**807**	**811**	**197**	**205**
Percentage of Patients Cured at Day 14 [units: percentage of participants]	**68.4**	**70.0**	**34.0**	**35.6**

No statistical analysis provided for Percentage of Patients Cured at Day 14

2. Secondary: Percentage of Patients Pain-Free at Day 14 [Time Frame: Day 14]

Measure Type	Secondary
Measure Title	Percentage of Patients Pain-Free at Day 14
Measure Description	Ocular pain as assessed by the investigator on a scale ranging from 0 (none) to 5 (severe). Pain-free was defined as a score of 0 on the investigator's assessment of ocular pain.
Time Frame	Day 14
Safety Issue	No

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.
All randomized patients with at least one postoperative assessment (ITT), last observation carried forward.

Reporting Groups

	Description
Nepafenac 0.3%	Nepafenac Ophthalmic Suspension, 0.3%, one drop in affected eye once daily for 16 days, beginning one day prior to surgery, continuing on the day of surgery, and for 14 days following surgery. An additional dose was administered between 30-120 minutes prior to surgery.
NEVANAC	Nepafenac Ophthalmic Suspension, 0.1%, one drop in affected eye three times daily, beginning one day prior to surgery, continuing on the day of surgery, and for 14 days following surgery.
Nepafenac Vehicle 0.3%	Nepafenac Ophthalmic Suspension 0.3% Vehicle, one drop in affected eye once daily for 16 days, beginning one day prior to surgery, continuing on the day of surgery, and for 14 days following surgery. An additional dose was administered between 30-120 minutes prior to surgery.
NEVANAC Vehicle	Nepafenac 0.1% vehicle, one drop in affected eye three times daily, beginning one day prior to surgery, continuing on the day of surgery, and for 14 days following surgery.

Measured Values

	Nepafenac 0.3%	**NEVANAC**	**Nepafenac Vehicle 0.3%**	**NEVANAC Vehicle**
Number of Participants Analyzed [units: participants]	**807**	**811**	**197**	**205**
Percentage of Patients Pain-Free at Day 14 [units: percentage of participants]	**91**	**90.9**	**49.7**	**56.1**

No statistical analysis provided for Percentage of Patients Pain-Free at Day 14

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Adverse events were collected for the duration of the study.
Additional Description	This reporting group includes all patients who received exposure to the study medication or potential exposure to the study medication: 2042. At each study visit, the patient received an ocular exam, and any changes in ocular and systemic medications and/or systemic disease/conditions since surgery were recorded.

Reporting Groups

	Description
Nepafenac 0.3%	Nepafenac Ophthalmic Suspension, 0.3%, one drop in affected eye once daily for 16 days, beginning one day prior to surgery, continuing on the day of surgery, and for 14 days following surgery. An additional dose was administered between 30-120 minutes prior to surgery.
NEVANAC	Nepafenac Ophthalmic Suspension, 0.1%, one drop in affected eye three times daily, beginning one day prior to

	surgery, continuing on the day of surgery, and for 14 days following surgery.
Nepafenac Vehicle 0.3%	Nepafenac Ophthalmic Suspension 0.3% Vehicle, one drop in affected eye once daily for 16 days, beginning one day prior to surgery, continuing on the day of surgery, and for 14 days following surgery. An additional dose was administered between 30-120 minutes prior to surgery.
NEVANAC Vehicle	Nepafenac 0.1% vehicle, one drop in affected eye three times daily, beginning one day prior to surgery, continuing on the day of surgery, and for 14 days following surgery.

Serious Adverse Events

	Nepafenac 0.3%	NEVANAC	Nepafenac Vehicle 0.3%	NEVANAC Vehicle
Total, serious adverse events				
# participants affected / at risk	**7/817 (0.86%)**	**3/819 (0.37%)**	**0/200 (0.00%)**	**0/206 (0.00%)**
Cardiac disorders				
Myocardial Infarction † 1 [3]				
# participants affected / at risk	**1/817 (0.12%)**	**0/819 (0.00%)**	**0/200 (0.00%)**	**0/206 (0.00%)**
Atrial Fibrillation † 1 [3]				
# participants affected / at risk	**0/817 (0.00%)**	**1/819 (0.12%)**	**0/200 (0.00%)**	**0/206 (0.00%)**
Infections and infestations				
Appendicitis † 1 [3]				
# participants affected / at risk	**1/817 (0.12%)**	**0/819 (0.00%)**	**0/200 (0.00%)**	**0/206 (0.00%)**
Sepsis † 1 [3]				
# participants affected / at risk	**0/817 (0.00%)**	**1/819 (0.12%)**	**0/200 (0.00%)**	**0/206 (0.00%)**
Injury, poisoning and procedural complications				
Injury † 1 [3]				
# participants affected / at risk	**2/817 (0.24%)**	**0/819 (0.00%)**	**0/200 (0.00%)**	**0/206 (0.00%)**
Metabolism and nutrition disorders				
Hyperkalaemia † 1 [3]				
# participants affected / at risk	**1/817 (0.12%)**	**0/819 (0.00%)**	**0/200 (0.00%)**	**0/206 (0.00%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Lung Carcinoma Cell Type Unspecified Stage IV † 1 [3]				
# participants affected / at risk	**1/817 (0.12%)**	**0/819 (0.00%)**	**0/200 (0.00%)**	**0/206 (0.00%)**
Nervous system disorders				
Brain Oedema † 1 [3]				
# participants affected / at risk	**1/817 (0.12%)**	**0/819 (0.00%)**	**0/200 (0.00%)**	**0/206 (0.00%)**
Cerebrovascular Accident † 1 [3]				
# participants affected / at risk	**1/817 (0.12%)**	**1/819 (0.12%)**	**0/200 (0.00%)**	**0/206 (0.00%)**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA (13.0)

[3] Not related

Other Adverse Events

Hide Other Adverse Events

Time Frame	Adverse events were collected for the duration of the study.
Additional Description	This reporting group includes all patients who received exposure to the study medication or potential exposure to the study medication: 2042. At each study visit, the patient received an ocular exam, and any changes in ocular and systemic medications and/or systemic disease/conditions since surgery were recorded.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Nepafenac 0.3%	Nepafenac Ophthalmic Suspension, 0.3%, one drop in affected eye once daily for 16 days, beginning one day prior to surgery, continuing on the day of surgery, and for 14 days following surgery. An additional dose was administered between 30-120 minutes prior to surgery.
NEVANAC	Nepafenac Ophthalmic Suspension, 0.1%, one drop in affected eye three times daily, beginning one day prior to surgery, continuing on the day of surgery, and for 14 days following surgery.
Nepafenac Vehicle 0.3%	Nepafenac Ophthalmic Suspension 0.3% Vehicle, one drop in affected eye once daily for 16 days, beginning one day prior to surgery, continuing on the day of surgery, and for 14 days following surgery. An additional dose was administered between 30-120 minutes prior to surgery.
NEVANAC Vehicle	Nepafenac 0.1% vehicle, one drop in affected eye three times daily, beginning one day prior to surgery, continuing on the day of surgery, and for 14 days following surgery.

Other Adverse Events

	Nepafenac 0.3%	**NEVANAC**	**Nepafenac Vehicle 0.3%**	**NEVANAC Vehicle**
Total, other (not including serious) adverse events				
# participants affected / at risk	**0/817 (0.00%)**	**0/819 (0.00%)**	**0/200 (0.00%)**	**0/206 (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
This study excluded patients who were under the age of 18, had uncontrolled glaucoma, were at risk of developing macular edema (eg, diabetic retinopathy), or of childbearing potential. Therefore, results may not be generalizable to these populations.

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: Sponsor reserves the right of prior review of any publication or presentation of information related to the study.

Results Point of Contact:

Name/Title: Dana Sager, Clinical Manager Group Leader
Organization: Alcon Research
phone: 1-817-551-8603
e-mail: dana.sager@alconlabs.com

No publications provided

Responsible Party:	Alcon Research
ClinicalTrials.gov Identifier:	NCT01109173 History of Changes
Other Study ID Numbers:	**C-09-055**
Study First Received:	April 21, 2010
Results First Received:	November 1, 2012
Last Updated:	November 29, 2012
Health Authority:	United States: Food and Drug Administration United States: Institutional Review Board Hungary: Ministry of Health, Social and Family Affairs Hungary: Institutional Ethics Committee Italy: Ministry of Health Italy: Ethics Committee Sweden: Institutional Review Board Sweden: Medical Products Agency Switzerland: Ethikkommission Switzerland: Federal Office of Public Health