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Trial record **1 of 1** for: C-11-034

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Travoprost 3-Month Safety and Efficacy Study

This study has been completed.

Sponsor:
Alcon Research

Information provided by (Responsible Party):
Alcon Research

ClinicalTrials.gov Identifier:
NCT01453855

First received: October 13, 2011
Last updated: August 13, 2013
Last verified: August 2013
History of Changes

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Results First Received: August 13, 2013

Study Type:	Interventional
Study Design:	Allocation: Randomized; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Conditions:	Open-Angle Glaucoma Ocular Hypertension
Interventions:	Drug: Travoprost ophthalmic solution, 0.003% Drug: Travoprost ophthalmic solution, 0.004%

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
Subjects were recruited from 60 investigational centers, including 52 in the US, 2 each in Sweden, Germany, and Austria, and 1 each in Spain and Finland.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
Of the 1099 enrolled, 235 did not meet inclusion/exclusion criteria and were exited from the study prior to randomization. This reporting group includes all randomized subjects (864).

Reporting Groups

	Description
Travoprost 0.003%	Travoprost ophthalmic solution, 0.003%, one drop instilled in each eye, once daily, for three months
TRAVATAN	Travoprost ophthalmic solution, 0.004%, one drop instilled in each eye, once daily, for three months

Participant Flow: Overall Study

	Travoprost 0.003%	**TRAVATAN**
STARTED	**442**	**422**

COMPLETED	**432**	**408**
NOT COMPLETED	**10**	**14**
Adverse Event	**3**	**4**
Lost to Follow-up	**2**	**1**
Patient Decision Unrel to Adverse Event	**3**	**3**
Noncompliance	**1**	**0**
Inadequate Control of IOP	**1**	**5**
Other	**0**	**1**

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.
This reporting group includes subjects exposed to the study medication. Note: One subject in the TRAVATAN arm was randomized but discontinued prior to exposure to study medication and is not included in this reporting group.

Reporting Groups

	Description
Travoprost 0.003%	Travoprost ophthalmic solution, 0.003%, one drop instilled in each eye, once daily, for three months
TRAVATAN	Travoprost ophthalmic solution, 0.004%, one drop instilled in each eye, once daily, for three months
Total	Total of all reporting groups

Baseline Measures

	Travoprost 0.003%	**TRAVATAN**	**Total**
Number of Participants [units: participants]	**442**	**421**	**863**
Age, Customized [units: Participants]			
18 to 64 years	**189**	**193**	**382**
≥ 65 years	**253**	**228**	**481**
Gender [units: participants]			
Female	**269**	**246**	**515**
Male	**173**	**175**	**348**

Outcome Measures

1. Primary: Mean Intraocular Pressure (IOP) at Week 2, Week 6, and Month 3 for Each Assessment Time Point (8 AM, 10 AM, and 4 PM) [Time Frame: Week 2, Week 6, Month 3 (8 AM, 10 AM, 4 PM)]

Hide Outcome Measure 1

Measure Type	Primary
	Mean Intraocular Pressure (IOP) at Week 2, Week 6, and Month 3 for Each Assessment Time Point (8 AM, 10 AM,

Measure Title	and 4 PM)
Measure Description	As measured by Goldmann applanation tonometry. One eye from each subject was chosen as the study eye and only the study eye was used in the efficacy analysis. A higher IOP can be a greater risk factor for developing glaucoma or glaucoma progression (leading to optic nerve damage).
Time Frame	Week 2, Week 6, Month 3 (8 AM, 10 AM, 4 PM)
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.
The intent-to-treat (ITT) analysis set included all patients who received study drug and completed at least 1 scheduled on-therapy study visit. In addition, no imputation methods were employed; therefore only efficacy measurements available at each visit and time point were analyzed.

Reporting Groups

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Measured Values

	Travoprost 0.003%	TRAVATAN
Number of Participants Analyzed [units: participants]	**442**	**416**
Mean Intraocular Pressure (IOP) at Week 2, Week 6, and Month 3 for Each Assessment Time Point (8 AM, 10 AM, and 4 PM) [units: millimeters mercury (mmHg)] Least Squares Mean (Standard Error)		
Week 2 at 8 AM	**19.4 (0.16)**	**19.5 (0.17)**
Week 2 at 10 AM	**18.6 (0.16)**	**18.6 (0.16)**
Week 2 at 4 PM	**18.0 (0.16)**	**18.3 (0.16)**
Week 6 at 8 AM	**19.3 (0.16)**	**19.3 (0.17)**
Week 6 at 10 AM	**18.5 (0.16)**	**18.6 (0.17)**
Week 6 at 4 PM	**18.0 (0.16)**	**18.1 (0.17)**
Month 3 at 8 AM	**19.2 (0.17)**	**19.3 (0.18)**
Month 3 at 10 AM	**18.3 (0.17)**	**18.6 (0.18)**
Month 3 at 4 PM	**18.0 (0.16)**	**18.0 (0.17)**

No statistical analysis provided for Mean Intraocular Pressure (IOP) at Week 2, Week 6, and Month 3 for Each Assessment Time Point (8 AM, 10 AM, and 4 PM)

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Adverse events were collected from time of enrollment to study completion. An adverse event was considered to be any untoward medical occurrence in a patient exposed to the study medication.
Additional Description	This reporting group includes subjects exposed to the study medication.

Reporting Groups

	Description
Travoprost 0.003%	Travoprost ophthalmic solution, 0.003%, one drop instilled in each eye, once daily, for three months
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Serious Adverse Events

	Travoprost 0.003%	TRAVATAN
Total, serious adverse events		
# participants affected / at risk	**5/442 (1.13%)**	**7/421 (1.66%)**
Cardiac disorders		
Myocardial infarction [1]		
# participants affected / at risk	**0/442 (0.00%)**	**1/421 (0.24%)**
Gastrointestinal disorders		
Abdominal pain [1]		
# participants affected / at risk	**1/442 (0.23%)**	**0/421 (0.00%)**
General disorders		
Chest Pain [1]		
# participants affected / at risk	**2/442 (0.45%)**	**0/421 (0.00%)**
Immune system disorders		
Drug hypersensitivity [1]		
# participants affected / at risk	**0/442 (0.00%)**	**1/421 (0.24%)**
Infections and infestations		
Gastroenteritis [1]		
# participants affected / at risk	**1/442 (0.23%)**	**0/421 (0.00%)**
Cellulitis [1]		
# participants affected / at risk	**0/442 (0.00%)**	**1/421 (0.24%)**
# events		**2**
Erysipelas [1]		
# participants affected / at risk	**0/442 (0.00%)**	**1/421 (0.24%)**
Injury, poisoning and procedural complications		
Collapse of lung [1]		
# participants affected / at risk	**1/442 (0.23%)**	**0/421 (0.00%)**
Injury [1]		
# participants affected / at risk	**1/442 (0.23%)**	**0/421 (0.00%)**
Metabolism and nutrition disorders		
Diabetes mellitus [1]		
# participants affected / at risk	**0/442 (0.00%)**	**1/421 (0.24%)**

Diabetic ketoacidosis [1]		
# participants affected / at risk	**0/442 (0.00%)**	**1/421 (0.24%)**
Renal and urinary disorders		
Nephrolithiasis [1]		
# participants affected / at risk	**0/442 (0.00%)**	**1/421 (0.24%)**
Respiratory, thoracic and mediastinal disorders		
Pneumothorax [1]		
# participants affected / at risk	**1/442 (0.23%)**	**0/421 (0.00%)**

1 Term from vocabulary, MedDRA 14.0

Other Adverse Events

Hide Other Adverse Events

Time Frame	Adverse events were collected from time of enrollment to study completion. An adverse event was considered to be any untoward medical occurrence in a patient exposed to the study medication.
Additional Description	This reporting group includes subjects exposed to the study medication.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
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Other Adverse Events

	Travoprost 0.003%	TRAVATAN
Total, other (not including serious) adverse events		
# participants affected / at risk	**56/442 (12.67%)**	**64/421 (15.20%)**
Eye disorders		
Ocular hyperaemia [1]		
# participants affected / at risk	**31/442 (7.01%)**	**34/421 (8.08%)**
Conjunctival hyperaemia [1]		
# participants affected / at risk	**25/442 (5.66%)**	**30/421 (7.13%)**

1 Term from vocabulary, MedDRA 14.0

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

Results Point of Contact:

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No publications provided

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