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Trial record **1 of 1** for: RDG-10-298

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Efficacy of Changing to TRAVATAN® From Prior Therapy

This study has been completed.

Sponsor:
Alcon Research

Information provided by (Responsible Party):
Alcon Research

ClinicalTrials.gov Identifier:
NCT01493427

First received: December 14, 2011
Last updated: May 9, 2014
Last verified: May 2014
History of Changes

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Results First Received: February 17, 2014

Study Type:	Interventional
Study Design:	Allocation: Non-Randomized; Intervention Model: Single Group Assignment; Masking: Open Label; Primary Purpose: Treatment
Conditions:	Open-Angle Glaucoma Ocular Hypertension
Intervention:	Drug: Travoprost 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 15 investigative sites located in Europe: Belgium (2); Spain (6); Italy (4); Sweden (3).

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
Of the 202 subjects enrolled, 1 subject was exited as a screen failure and 2 subjects withdrew consent prior to dosing. This reporting group includes all subjects who instilled at least one dose of the test article (199).

Reporting Groups

	Description
TRAVATAN® BAK-free	Travoprost 0.004%, 1 drop self-administered to the study eye(s) once daily, every evening at around 8:00 pm, for 12 weeks Travoprost 0.004%: Travoprost 0.004% without benzalkonium chloride (BAK), containing Polyquad (PQ) preservative

Participant Flow: Overall Study

	TRAVATAN® BAK-free
STARTED	**199**
COMPLETED	**179**

NOT COMPLETED	**20**
Adverse Event	**10**
Personal Reasons	**4**
Lost to Follow-up	**2**
Inability to Follow Instructions	**2**
Other	**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.
This reporting group includes all subjects who instilled at least one dose of the test article

Reporting Groups

	Description
TRAVATAN® BAK-free	Travoprost 0.004%, 1 drop self-administered to the study eye(s) once daily, every evening at around 8:00 pm, for 12 weeks Travoprost 0.004%: Travoprost 0.004% without benzalkonium chloride (BAK), containing Polyquad (PQ) preservative

Baseline Measures

	TRAVATAN® BAK-free
Number of Participants [units: participants]	**199**
Age [units: years] Mean (Standard Deviation)	**66.6 (11.7)**
Gender [units: participants]	
Female	**117**
Male	**82**

Outcome Measures

Hide All Outcome Measures

1. Primary: Mean Change in Intraocular Pressure (IOP) at 12 Weeks From Prior Therapy (Baseline) [Time Frame: Baseline, Week 12]

Measure Type	Primary
Measure Title	Mean Change in Intraocular Pressure (IOP) at 12 Weeks From Prior Therapy (Baseline)
Measure Description	IOP (fluid pressure inside the eye) was measured by Goldmann applanation tonometry. A higher IOP can be a greater risk for developing glaucoma or glaucoma progression (leading to optic nerve damage). A more negative change indicates a greater amount of improvement. One eye was chosen as the study eye, and only data from the study eye were used for the efficacy analysis.
Time Frame	Baseline, Week 12
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 Full Analysis Set (FA) included all subjects who instilled at least one drop of study product and who had primary endpoints measures available for at least one on-therapy study visit (N=187). Here, "n" is the number of participants with non-missing values at the specific time point.

Reporting Groups

	Description
TRAVATAN® BAK-free	Travoprost 0.004%, 1 drop self-administered to the study eye(s) once daily, every evening at around 8:00 pm, for 12 weeks

Measured Values

	TRAVATAN® BAK-free
Number of Participants Analyzed [units: participants]	**187**
Mean Change in Intraocular Pressure (IOP) at 12 Weeks From Prior Therapy (Baseline) [units: millimeters mercury (mmHg)] Mean (Standard Deviation)	
Baseline	**17.0 (3.3)**
Change from Baseline at Week 12 (n=178)	**-1.16 (2.65)**

No statistical analysis provided for Mean Change in Intraocular Pressure (IOP) at 12 Weeks From Prior Therapy (Baseline)

2. Secondary: Percentage of Patients With Target IOP (≤18 mmHg) at 12 Weeks [Time Frame: Week 12]

Measure Type	Secondary
Measure Title	Percentage of Patients With Target IOP (≤18 mmHg) at 12 Weeks
Measure Description	IOP (fluid pressure inside the eye) was measured by Goldmann applanation tonometry. A higher IOP can be a greater risk for developing glaucoma or glaucoma progression (leading to optic nerve damage). One eye was chosen as the study eye, and only data from the study eye were used for the efficacy analysis.
Time Frame	Week 12
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 Full Analysis Set (FA) included all subjects who instilled at least one drop of study product and who had primary endpoints measures available for at least one on-therapy study visit.

Reporting Groups

	Description
TRAVATAN® BAK-free	Travoprost 0.004%, 1 drop self-administered to the study eye(s) once daily, every evening at around 8:00 pm, for 12 weeks

Measured Values

	TRAVATAN® BAK-free
Number of Participants Analyzed	

[units: participants]	**187**
Percentage of Patients With Target IOP (≤18 mmHg) at 12 Weeks [units: Percentage of participants]	**81.2**

No statistical analysis provided for Percentage of Patients With Target IOP (≤18 mmHg) at 12 Weeks

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Adverse event data were collected and reported in the eCRF at each visit from time of first drug instillation to Week 12. Adverse events were collected for the duration of the study (1 year, 2 months).
Additional Description	This reporting group includes all subjects who instilled at least one dose of the test article.

Reporting Groups

	Description
TRAVATAN® BAK-free	Travoprost 0.004%, 1 drop self-administered to the study eye(s) once daily, every evening at around 8:00 pm, for 12 weeks Travoprost 0.004%: Travoprost 0.004% without benzalkonium chloride (BAK), containing Polyquad (PQ) preservative

Serious Adverse Events

	TRAVATAN® BAK-free
Total, serious adverse events	
# participants affected / at risk	**4/199 (2.01%)**
Gastrointestinal disorders	
Upper gastrointestinal hemmorhage † 1	
# participants affected / at risk	**1/199 (0.50%)**
Hepatobiliary disorders	
Cholelithiasis † 1	
# participants affected / at risk	**1/199 (0.50%)**
Infections and infestations	
Pneumonia pneumococcal † 1	
# participants affected / at risk	**1/199 (0.50%)**
Respiratory tract infection † 1	
# participants affected / at risk	**1/199 (0.50%)**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 15.0

Other Adverse Events

Hide Other Adverse Events

Time Frame	Adverse event data were collected and reported in the eCRF at each visit from time of first drug instillation to Week 12. Adverse events were collected for the duration of the study (1 year, 2 months).
Additional Description	This reporting group includes all subjects who instilled at least one dose of the test article.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
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Other Adverse Events

	TRAVATAN® BAK-free
Total, other (not including serious) adverse events	
# participants affected / at risk	**0/199 (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
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:

Name/Title: Doug Hubatsch, Global Brand Leader, Medical Affairs
Organization: Alcon Research, Ltd.
phone: 1-888-451-3937
e-mail: alcon.medinfo@alcon.com

No publications provided

Responsible Party: Alcon Research

ClinicalTrials.gov Identifier:	NCT01493427 History of Changes
Other Study ID Numbers:	**RDG-10-298** 2011-000161-13 (EudraCT Number)
Study First Received:	December 14, 2011
Results First Received:	February 17, 2014
Last Updated:	May 9, 2014
Health Authority:	Belgium: Ethics Committee Spain: Ethics Committee Sweden: Institutional Review Board Italy: Ethics Committee