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Trial record **1 of 1** for: C-08-40

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Efficacy Study of Travoprost APS Versus TRAVATAN

This study has been completed.

Sponsor:
Alcon Research

Information provided by (Responsible Party):
Alcon Research

ClinicalTrials.gov Identifier:
NCT00848536

First received: February 19, 2009
Last updated: April 4, 2012
Last verified: April 2012
History of Changes

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Results First Received: February 14, 2011

Study Type:	Interventional
Study Design:	Allocation: Randomized; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
Conditions:	Open Angle Glaucoma Ocular Hypertension
Interventions:	Drug: Travoprost 0.004% (POLYQUAD-preserved) Eye Drops, Solution Drug: Travoprost 0.004% (BAK-preserved) Eye Drops, Solution

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 recruited from 30 study centers: 8 in the US, 6 in Mexico, 2 in Brazil, 4 in India, 2 in Australia, 2 in New Zealand, 2 in Latvia, and a single site in each: Taiwan, France, Belgium, and Italy.

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
TRAVATAN APS	One drop once daily in the evening for 3 months
TRAVATAN	One drop once daily in the evening for 3 months

Participant Flow: Overall Study

	TRAVATAN APS	**TRAVATAN**
STARTED	**185**	**186**
COMPLETED	**181**	**179**

NOT COMPLETED	**4**	**7**
Adverse Event	**2**	**2**
Withdrawal by Subject	**0**	**1**
Protocol Violation	**0**	**1**
Noncompliance	**1**	**0**
Inadequate Control of IOP	**1**	**1**
Patient Moved	**0**	**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
TRAVATAN APS	One drop once daily in the evening for 3 months
TRAVATAN	One drop once daily in the evening for 3 months
Total	Total of all reporting groups

Baseline Measures

	TRAVATAN APS	TRAVATAN	Total
Number of Participants [units: participants]	**185**	**186**	**371**
Age [units: participants]			
<=18 years	**0**	**0**	**0**
Between 18 and 65 years	**94**	**109**	**203**
>=65 years	**91**	**77**	**168**
Gender [units: participants]			
Female	**112**	**115**	**227**
Male	**73**	**71**	**144**

Outcome Measures

Hide All Outcome Measures

1. Primary: Mean Intraocular Pressure at 9:00 am [Time Frame: 3 months (measured at 9:00 am)]

Measure Type	Primary
Measure Title	Mean Intraocular Pressure at 9:00 am
Measure Description	For an individual patient, two consecutive IOP measurements for each eye were taken. The mean IOP values for each

	individual patient's eye were rounded up to the next whole number if the value was ≥ 0.5 mmHg All IOP measurements were performed with a Goldmann applanation tonometer. All IOP measurements for any individual subject were to be performed preferably by the same operator using the same tonometer. Mean IOP for the patient's worse eye at baseline was used in the primary endpoint analysis. If both eyes were equal, then the right eye was selected for analysis
Time Frame	3 months (measured at 9:00 am)
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.
Per-Protocol. Patients who received study medication, satisfied pre-randomization criteria and satisfied protocol criteria at the specific time point were considered evaluable for PP analysis.

Reporting Groups

	Description
TRAVATAN APS	One drop once daily in the evening for 3 months
TRAVATAN	One drop once daily in the evening for 3 months

Measured Values

	TRAVATAN APS	**TRAVATAN**
Number of Participants Analyzed [units: participants]	**172**	**172**
Mean Intraocular Pressure at 9:00 am [units: mmHg] Least Squares Mean (Standard Error)	**17.9 (0.25)**	**18.1 (0.25)**

Statistical Analysis 1 for Mean Intraocular Pressure at 9:00 am

Groups [1]	All groups
Non-Inferiority/Equivalence Test [2]	Yes
Mean Difference (Final Values) [3]	-0.2
Standard Error of the mean	(0.35)
95% Confidence Interval	-0.9 to 0.5

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	A hypothesis test was performed using a repeated measures analysis of variance model. For the test of non-inferiority, a two-sided 95% confidence intervals for the treatment group difference in mean IOP at each visit and time point was constructed based on analysis of variance.
[2]	Details of power calculation, definition of non-inferiority margin, and other key parameters:
	The non-inferiority margin was 1.5 mmHg.
[3]	Other relevant estimation information:
	Treatment group differences were calculated as the mean IOP in the Travoprost APS group minus the mean IOP in the Travatan group. Non-inferiority was demonstrated if the upper 95% CL of the between treatment difference in mean IOP was < 1.5 mmHg.

2. Primary: Mean Intraocular Pressure at 11:00 am [Time Frame: 3 months (measured at 11:00 am)]

Measure Type	Primary
Measure Title	Mean Intraocular Pressure at 11:00 am
Measure Description	For an individual patient, two consecutive IOP measurements for each eye were taken. The mean IOP values for each individual patient's eye were rounded up to the next whole number if the value was ≥ 0.5 mmHg All IOP measurements were performed with a Goldmann applanation tonometer. All IOP measurements for any individual subject were to be performed preferably by the same operator using the same tonometer. Mean IOP for the patient's worse eye at baseline was used in the primary endpoint analysis. If both eyes were equal, then the right eye was selected for analysis
Time Frame	3 months (measured at 11:00 am)
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.
Per-Protocol. Patients who received study medication, satisfied pre-randomization criteria and satisfied protocol criteria at the specific time point were considered evaluable for PP analysis.

Reporting Groups

	Description
TRAVATAN APS	One drop once daily in the evening for 3 months
TRAVATAN	One drop once daily in the evening for 3 months

Measured Values

	TRAVATAN APS	**TRAVATAN**
Number of Participants Analyzed [units: participants]	**171**	**171**
Mean Intraocular Pressure at 11:00 am [units: mmHg] Least Squares Mean (Standard Error)	**17.4 (0.25)**	**17.5 (0.25)**

Statistical Analysis 1 for Mean Intraocular Pressure at 11:00 am

Groups [1]	All groups
Non-Inferiority/Equivalence Test [2]	Yes
Median Difference (Final Values) [3]	-0.1
Standard Error of the mean	(0.35)
95% Confidence Interval	-0.8 to 00.6

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	A hypothesis test was performed using a repeated measures analysis of variance model. For the test of non-inferiority, a two-sided 95% confidence intervals for the treatment group difference in mean IOP at each visit and time point was constructed based on analysis of variance.
[2]	Details of power calculation, definition of non-inferiority margin, and other key parameters:
	The non-inferiority margin was 1.5 mmHg.
[3]	Other relevant estimation information:
	Treatment group differences were calculated as the mean IOP in the Travoprost APS group minus the mean IOP in the Travatan group. Non-inferiority was demonstrated if the upper 95% CL of the between treatment difference in mean IOP was < 1.5 mmHg.

3. Primary: Mean Intraocular Pressure at 4:00 pm [Time Frame: 3 months (measured at 4:00 pm)]

Measure Type	Primary
Measure Title	Mean Intraocular Pressure at 4:00 pm
Measure Description	For an individual patient, two consecutive IOP measurements for each eye were taken. The mean IOP values for each individual patient's eye were rounded up to the next whole number if the value was ≥ 0.5 mmHg All IOP measurements were performed with a Goldmann applanation tonometer. All IOP measurements for any individual subject were to be performed preferably by the same operator using the same tonometer. Mean IOP for the patient's worse eye at baseline was used in the primary endpoint analysis. If both eyes were equal, then the right eye was selected for analysis
Time Frame	3 months (measured at 4:00 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.
Per-Protocol. Patients who received study medication, satisfied pre-randomization criteria and satisfied protocol criteria at the specific time point were considered evaluable for PP analysis.

Reporting Groups

	Description
TRAVATAN APS	One drop once daily in the evening for 3 months
TRAVATAN	One drop once daily in the evening for 3 months

Measured Values

	TRAVATAN APS	**TRAVATAN**
Number of Participants Analyzed [units: participants]	**171**	**171**
Mean Intraocular Pressure at 4:00 pm [units: mmHg] Least Squares Mean (Standard Error)	**16.9 (0.25)**	**17.1 (0.25)**

Statistical Analysis 1 for Mean Intraocular Pressure at 4:00 pm

Groups [1]	All groups
Non-Inferiority/Equivalence Test [2]	Yes
Median Difference (Final Values) [3]	-0.2
Standard Error of the mean	(0.35)
95% Confidence Interval	-0.9 to 0.5

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	A hypothesis test was performed using a repeated measures analysis of variance model. For the test of non-inferiority, a two-sided 95% confidence intervals for the treatment group difference in mean IOP at each visit and time point was constructed based on analysis of variance.
[2]	Details of power calculation, definition of non-inferiority margin, and other key parameters:
	The non-inferiority margin was 1.5 mmHg.

[3]	Other relevant estimation information:
	Treatment group differences were calculated as the mean IOP in the Travoprost APS group minus the mean IOP in the Travatan group. Non-inferiority was demonstrated if the upper 95% CL of the between treatment difference in mean IOP was < 1.5 mmHg.

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	3 Months
Additional Description	No text entered.

Reporting Groups

	Description
TRAVATAN APS	One drop once daily in the evening for 3 months
TRAVATAN	One drop once daily in the evening for 3 months

Serious Adverse Events

	TRAVATAN APS	TRAVATAN
Total, serious adverse events		
# participants affected / at risk	**1/185 (0.54%)**	**2/186 (1.08%)**
Gastrointestinal disorders		
Abdominal mass * 1		
# participants affected / at risk	**1/185 (0.54%)**	**0/186 (0.00%)**
# events	**1**	**0**
General disorders		
Chest pain * 1		
# participants affected / at risk	**0/185 (0.00%)**	**1/186 (0.54%)**
# events	**0**	**1**
Infections and infestations		
Pneumonia * 1		
# participants affected / at risk	**0/185 (0.00%)**	**1/186 (0.54%)**
# events	**0**	**1**

* Events were collected by non-systematic assessment

1 Term from vocabulary, MedDRA Version 12.0

Other Adverse Events

Hide Other Adverse Events

Time Frame	3 Months
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
TRAVATAN APS	One drop once daily in the evening for 3 months
TRAVATAN	One drop once daily in the evening for 3 months

Other Adverse Events

	TRAVATAN APS	TRAVATAN
Total, other (not including serious) adverse events		
# participants affected / at risk	**32/185 (17.30%)**	**35/186 (18.82%)**
Eye disorders		
Ocular hyperaemia * 1		
# participants affected / at risk	**21/185 (11.35%)**	**19/186 (10.22%)**
# events	**22**	**22**
Eye irritation * 1		
# participants affected / at risk	**7/185 (3.78%)**	**11/186 (5.91%)**
# events	**8**	**12**
Conjunctival hyperaemia * 1		
# participants affected / at risk	**8/185 (4.32%)**	**10/186 (5.38%)**
# events	**9**	**10**

* Events were collected by non-systematic assessment
1 Term from vocabulary, MedDRA Version 12.0

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.

Results Point of Contact:

Name/Title: Director Alcon Clinical

Organization: Alcon Research, Ltd.
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No publications provided

Responsible Party:	Alcon Research
ClinicalTrials.gov Identifier:	NCT00848536 History of Changes
Other Study ID Numbers:	**C-08-40** 2008-006027-31 (EudraCT Number)
Study First Received:	February 19, 2009
Results First Received:	February 14, 2011
Last Updated:	April 4, 2012
Health Authority:	United States: Food and Drug Administration United States: Institutional Review Board