Trial record **1 of 1** for: SMA-08-16
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Efficacy and Safety of Travoprost 0.004% Versus Tafluprost 0.0015% in Patients With Primary Open-angle Glaucoma or Ocular Hypertension

This study has been completed.

Sponsor:
Alcon Research

Information provided by (Responsible Party):
Alcon Research

ClinicalTrials.gov Identifier:
NCT00966940

First received: August 26, 2009
Last updated: May 18, 2012
Last verified: May 2012
History of Changes

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Results First Received: February 9, 2011

Study Type:	Interventional
Study Design:	Allocation: Randomized; Intervention Model: Crossover Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
Condition:	Glaucoma
Interventions:	Drug: Travoprost 0.004% ophthalmic solution (TRAVATAN) Drug: Tafluprost 0.0015% ophthalmic 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 four private practices located in Germany.

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
Travoprost-to-tafluprost	Travoprost, then tafluprost
Tafluprost-to-travoprost	Tafluprost, then travoprost

Participant Flow for 2 periods

Period 1: Period 1, First 6 Weeks

	Travoprost-to-tafluprost	**Tafluprost-to-travoprost**
STARTED	**28**	**23**

COMPLETED	**25**	**23**
NOT COMPLETED	**3**	**0**
Withdrawal by Subject	**2**	**0**
Protocol Violation	**1**	**0**

Period 2: Period 2, Second 6 Weeks

	Travoprost-to-tafluprost	Tafluprost-to-travoprost
STARTED	**25**	**23**
COMPLETED	**25**	**23**
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
Travoprost-to-tafluprost	Travoprost, then tafluprost
Tafluprost-to-travoprost	Tafluprost, then travoprost
Total	Total of all reporting groups

Baseline Measures

	Travoprost-to-tafluprost	Tafluprost-to-travoprost	Total
Number of Participants [units: participants]	**28**	**23**	**51**
Age [units: years] Mean (Standard Deviation)	**69.1 (7.8)**	**68.5 (10.5)**	**68.8 (9.0)**
Gender [units: participants]			
Female	**16**	**15**	**31**
Male	**12**	**8**	**20**

Outcome Measures

Hide All Outcome Measures

1. Primary: Mean Intraocular Pressure (IOP) at 8:00 PM [Time Frame: 6 weeks]

Measure Type	Primary
Measure Title	Mean Intraocular Pressure (IOP) at 8:00 PM
Measure Description	Intraocular pressure was measured by Goldmann applanation tonometry.

Time Frame	6 weeks
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.
This reporting group includes all patients randomized to both periods of the study and exposed to both study drugs.

Reporting Groups

	Description
Travoprost	One drop in the qualifying eye(s) each evening at 6:00 PM for six weeks, administered topically
Tafluprost	One drop in the qualifying eye(s) each evening at 6:00 PM for six weeks, administered topically

Measured Values

	Travoprost	**Tafluprost**
Number of Participants Analyzed [units: participants]	**48**	**48**
Mean Intraocular Pressure (IOP) at 8:00 PM [units: mm Hg] Mean (Standard Deviation)	**17.1 (3.17)**	**17.7 (3.23)**

No statistical analysis provided for Mean Intraocular Pressure (IOP) at 8:00 PM

2. Secondary: Mean Intraocular Pressure (IOP) at 8:00 AM [Time Frame: 6 weeks]

Measure Type	Secondary
Measure Title	Mean Intraocular Pressure (IOP) at 8:00 AM
Measure Description	Intraocular pressure was measured by Goldmann applanation tonometry.
Time Frame	6 weeks
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.
This reporting group includes all patients randomized to both periods of the study and exposed to both study drugs.

Reporting Groups

	Description
Travoprost	One drop in the qualifying eye(s) each evening at 6:00 PM for six weeks, administered topically
Tafluprost	One drop in the qualifying eye(s) each evening at 6:00 PM for six weeks, administered topically

Measured Values

	Travoprost	**Tafluprost**
Number of Participants Analyzed [units: participants]	**48**	**48**
Mean Intraocular Pressure (IOP) at 8:00 AM [units: mm Hg]	**17.0 (2.36)**	**17.5 (2.20)**

Mean (Standard Deviation)		

No statistical analysis provided for Mean Intraocular Pressure (IOP) at 8:00 AM

3. Secondary: Mean Intraocular Pressure (IOP) at 10:00 AM [Time Frame: 6 weeks]

Measure Type	Secondary
Measure Title	Mean Intraocular Pressure (IOP) at 10:00 AM
Measure Description	Intraocular pressure was measured by Goldmann applanation tonometry.
Time Frame	6 weeks
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.
This reporting group includes all patients randomized to both periods of the study and exposed to both study drugs.

Reporting Groups

	Description
Travoprost	One drop in the qualifying eye(s) each evening at 6:00 PM for six weeks, administered topically
Tafluprost	One drop in the qualifying eye(s) each evening at 6:00 PM for six weeks, administered topically

Measured Values

	Travoprost	**Tafluprost**
Number of Participants Analyzed [units: participants]	**48**	**48**
Mean Intraocular Pressure (IOP) at 10:00 AM [units: mm Hg] Mean (Standard Deviation)	**16.7 (2.39)**	**17.3 (2.50)**

No statistical analysis provided for Mean Intraocular Pressure (IOP) at 10:00 AM

4. Secondary: Mean Intraocular Pressure (IOP) at 12:00 PM [Time Frame: 6 weeks]

Measure Type	Secondary
Measure Title	Mean Intraocular Pressure (IOP) at 12:00 PM
Measure Description	Intraocular pressure was measured by Goldmann applanation tonometry.
Time Frame	6 weeks
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.
This reporting group includes all patients randomized to both periods of the study and exposed to both study drugs.

Reporting Groups

	Description
Travoprost	One drop in the qualifying eye(s) each evening at 6:00 PM for six weeks, administered topically
Tafluprost	One drop in the qualifying eye(s) each evening at 6:00 PM for six weeks, administered topically

Measured Values

	Travoprost	Tafluprost
Number of Participants Analyzed [units: participants]	**48**	**48**
Mean Intraocular Pressure (IOP) at 12:00 PM [units: mm Hg] Mean (Standard Deviation)	**16.7 (2.47)**	**17.2 (2.46)**

No statistical analysis provided for Mean Intraocular Pressure (IOP) at 12:00 PM

5. Secondary: Mean Intraocular Pressure (IOP) at 2:00 PM [Time Frame: 6 weeks]

Measure Type	Secondary
Measure Title	Mean Intraocular Pressure (IOP) at 2:00 PM
Measure Description	Intraocular pressure was measured by Goldmann applanation tonometry.
Time Frame	6 weeks
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.
This reporting group includes all patients randomized to both periods of the study and exposed to both study drugs.

Reporting Groups

	Description
Travoprost	One drop in the qualifying eye(s) each evening at 6:00 PM for six weeks, administered topically
Tafluprost	One drop in the qualifying eye(s) each evening at 6:00 PM for six weeks, administered topically

Measured Values

	Travoprost	Tafluprost
Number of Participants Analyzed [units: participants]	**48**	**48**
Mean Intraocular Pressure (IOP) at 2:00 PM [units: mm Hg] Mean (Standard Deviation)	**16.9 (2.69)**	**17.3 (2.77)**

No statistical analysis provided for Mean Intraocular Pressure (IOP) at 2:00 PM

6. Secondary: Mean Intraocular Pressure (IOP) at 4:00 PM [Time Frame: 6 weeks]

Measure Type	Secondary
Measure Title	Mean Intraocular Pressure (IOP) at 4:00 PM

Measure Description	Intraocular pressure was measured by Goldmann applanation tonometry.
Time Frame	6 weeks
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.
This reporting group includes all patients randomized to both periods of the study and exposed to both study drugs.

Reporting Groups

	Description
Travoprost	One drop in the qualifying eye(s) each evening at 6:00 PM for six weeks, administered topically
Tafluprost	One drop in the qualifying eye(s) each evening at 6:00 PM for six weeks, administered topically

Measured Values

	Travoprost	**Tafluprost**
Number of Participants Analyzed [units: participants]	**48**	**48**
Mean Intraocular Pressure (IOP) at 4:00 PM [units: mm Hg] Mean (Standard Deviation)	**17.1 (2.85)**	**17.6 (2.80)**

No statistical analysis provided for Mean Intraocular Pressure (IOP) at 4:00 PM

7. Secondary: Mean Intraocular Pressure (IOP) at 6:00 PM [Time Frame: 6 weeks]

Measure Type	Secondary
Measure Title	Mean Intraocular Pressure (IOP) at 6:00 PM
Measure Description	Intraocular pressure was measured by Goldmann applanation tonometry.
Time Frame	6 weeks
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.
This reporting group includes all patients randomized to both periods of the study and exposed to both study drugs.

Reporting Groups

	Description
Travoprost	One drop in the qualifying eye(s) each evening at 6:00 PM for six weeks, administered topically
Tafluprost	One drop in the qualifying eye(s) each evening at 6:00 PM for six weeks, administered topically

Measured Values

	Travoprost	**Tafluprost**
Number of Participants Analyzed [units: participants]	**48**	**48**
Mean Intraocular Pressure (IOP) at 6:00 PM		

[units: mm Hg] Mean (Standard Deviation)	**16.9 (3.12)**	**17.6 (3.13)**

No statistical analysis provided for Mean Intraocular Pressure (IOP) at 6:00 PM

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Adverse events were collected for the duration of the study: 10-September-2009 to 2-March-2010.
Additional Description	No text entered.

Reporting Groups

	Description
Travoprost	One drop in the qualifying eye(s) each evening at 6:00 PM for six weeks, administered topically
Tafluprost	One drop in the qualifying eye(s) each evening at 6:00 PM for six weeks, administered topically

Serious Adverse Events

	Travoprost	Tafluprost
Total, serious adverse events		
# participants affected / at risk	**0/51 (0.00%)**	**0/48 (0.00%)**

Other Adverse Events

Hide Other Adverse Events

Time Frame	Adverse events were collected for the duration of the study: 10-September-2009 to 2-March-2010.
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Travoprost	One drop in the qualifying eye(s) each evening at 6:00 PM for six weeks, administered topically
Tafluprost	One drop in the qualifying eye(s) each evening at 6:00 PM for six weeks, administered topically

Other Adverse Events

	Travoprost	Tafluprost
Total, other (not including serious) adverse events		
# participants affected / at risk	**0/51 (0.00%)**	**0/48 (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.

Results Point of Contact:

Name/Title: Director of Medical Affairs
Organization: Alcon Research, Ltd.
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No publications provided

Responsible Party:	Alcon Research
ClinicalTrials.gov Identifier:	NCT00966940 History of Changes
Other Study ID Numbers:	**SMA-08-16**
Study First Received:	August 26, 2009
Results First Received:	February 9, 2011
Last Updated:	May 18, 2012
Health Authority:	Germany: Ethics Commission