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Trial record **1 of 1** for: RDG-10-272

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Efficacy of Changing to DUOTRAV® From Prior Therapy

This study has been completed.

Sponsor:
Alcon Research

Information provided by (Responsible Party):
Alcon Research

ClinicalTrials.gov Identifier:
NCT01327599

First received: March 30, 2011
Last updated: January 13, 2014
Last verified: January 2014
History of Changes

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Results First Received: November 22, 2013

Study Type:	Interventional
Study Design:	Intervention Model: Single Group Assignment; Masking: Open Label; Primary Purpose: Treatment
Conditions:	Open-Angle Glaucoma Ocular Hypertension Pigment Dispersion Glaucoma
Intervention:	Drug: Travoprost 0.004%+Timolol 0.5% 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
Participants were recruited from 10 study centers in France and 3 study centers in Germany.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
This reporting group includes all enrolled participants.

Reporting Groups

	Description
DUOTRAV®	Travoprost 0.004%+Timolol 0.5% ophthalmic solution, 1 drop to the study eye(s) once a day at 8:00 PM for 12 weeks

Participant Flow: Overall Study

	DUOTRAV®
STARTED	**60**
COMPLETED	**57**
NOT COMPLETED	**3**

Adverse Event	**1**
Could Not Attend Visit	**1**
Withdrawal of Consent	**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 all participants who received study medication and had at least one on-therapy study visit (Intent-to-treat).

Reporting Groups

	Description
DUOTRAV®	Travoprost 0.004%+Timolol 0.5% ophthalmic solution, 1 drop to the study eye(s) once a day at 8:00 PM for 12 weeks

Baseline Measures

	DUOTRAV®
Number of Participants [units: participants]	**59**
Age [units: years] Mean (Standard Deviation)	**73.2 (9.8)**
Gender [units: participants]	
Female	**38**
Male	**21**

Outcome Measures

Hide All Outcome Measures

1. Primary: Mean Change From Baseline in IOP at Week 12 in Subjects Using Ganfort® at Baseline [Time Frame: Week 12]

Measure Type	Primary
Measure Title	Mean Change From Baseline in IOP at Week 12 in Subjects Using Ganfort® at Baseline
Measure Description	IOP (fluid pressure in the eye) was measured with Goldmann applanation tonometry. A positive number change from baseline indicates an increase in intraocular pressure, which may be a risk factor for developing glaucoma or glaucoma progression (leading to optic nerve damage). One eye was chosen as the study eye, and only the study eye was used for 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.
All subjects using Ganfort at baseline who received study medication and attended Week 12 visit.

Reporting Groups

	Description
DUOTRAV®	Travoprost 0.004%+Timolol 0.5% ophthalmic solution, 1 drop to the study eye(s) once a day at 8:00 PM for 12 weeks

Measured Values

	DUOTRAV®
Number of Participants Analyzed [units: participants]	**55**
Mean Change From Baseline in IOP at Week 12 in Subjects Using Ganfort® at Baseline [units: millimeters mercury (mmHg)] Mean (Standard Deviation)	
Baseline (Day 1)	**20.0 (1.0)**
Change from baseline at Week 12	**-3.8 (1.9)**

No statistical analysis provided for Mean Change From Baseline in IOP at Week 12 in Subjects Using Ganfort® at Baseline

2. Secondary: Mean Change From Baseline in Ocular Surface Disease Index (OSDI) Score at Week 12 in Subjects Using Ganfort® at Baseline [Time Frame: Week 12]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in Ocular Surface Disease Index (OSDI) Score at Week 12 in Subjects Using Ganfort® at Baseline
Measure Description	The OSDI is a 12-item quality of life questionnaire designed to assess ocular surface symptoms, their severity, and their impact on the subject's ability to function. Each item was scored by the subject on a 0-4 Likert-type scale (0=None, 4=All of the Time), with a resultant overall score of 0-100 (0=no disability, 100=complete disability). A negative number change from baseline represents a perceived improvement in ocular health.
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.
ITT: All subjects using Ganfort at baseline who received study medication and had at least one on-therapy study visit, minus missing responses.

Reporting Groups

	Description
DUOTRAV®	Travoprost 0.004%+Timolol 0.5% ophthalmic solution, 1 drop to the study eye(s) once a day at 8:00 PM for 12 weeks

Measured Values

	DUOTRAV®
Number of Participants Analyzed [units: participants]	**57**
Mean Change From Baseline in Ocular Surface Disease Index (OSDI) Score at Week 12 in Subjects Using Ganfort® at Baseline [units: Units on a scale] Mean (Standard Deviation)	
Baseline (Day 1)	**14.9 (10.9)**
Change from Baseline at Week 12	**-3.6 (6.5)**

No statistical analysis provided for Mean Change From Baseline in Ocular Surface Disease Index (OSDI) Score at Week 12 in Subjects Using Ganfort® at Baseline

3. Secondary: Mean Change From Baseline in Ocular Hyperemia Score at Week 12 in Subjects Using Ganfort® at Baseline [Time Frame: Week 12]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in Ocular Hyperemia Score at Week 12 in Subjects Using Ganfort® at Baseline
Measure Description	Ocular hyperemia (visible eye redness) was assessed during slit lamp examination and graded on a 5-point scale (0=none, 4=severe). A positive number change from baseline indicates an increase in ocular redness. One eye was chosen as the study eye, and only the study eye was used for 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.
ITT: All subjects using Ganfort at baseline who received study medication and had at least one on-therapy study visit, minus missing responses.

Reporting Groups

	Description
DUOTRAV®	Travoprost 0.004%+Timolol 0.5% ophthalmic solution, 1 drop to the study eye(s) once a day at 8:00 PM for 12 weeks

Measured Values

	DUOTRAV®
Number of Participants Analyzed [units: participants]	**57**
Mean Change From Baseline in Ocular Hyperemia Score at Week 12 in Subjects Using Ganfort® at Baseline [units: units on a scale] Mean (Standard Deviation)	**-0.1 (0.7)**

No statistical analysis provided for Mean Change From Baseline in Ocular Hyperemia Score at Week 12 in Subjects Using Ganfort® at Baseline

4. Secondary: Percentage of Subjects Who Reach Target IOP of ≤ 18 mmHg in Subjects Using Ganfort® at Baseline [Time Frame: Week 4, Week 12]

Measure Type	Secondary
Measure Title	Percentage of Subjects Who Reach Target IOP of ≤ 18 mmHg in Subjects Using Ganfort® at Baseline
Measure Description	IOP (fluid pressure in the eye) was measured with Goldmann applanation tonometry. An increase in intraocular pressure may be a risk factor for developing glaucoma or glaucoma progression (leading to optic nerve damage). One eye was chosen as the study eye, and only the study eye was used for analysis.
Time Frame	Week 4, 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.
ITT: All subjects using Ganfort at baseline who received study medication and had at least one on-therapy study visit, minus missing responses.

Reporting Groups

	Description
DUOTRAV®	Travoprost 0.004%+Timolol 0.5% ophthalmic solution, 1 drop to the study eye(s) once a day at 8:00 PM for 12 weeks

Measured Values

	DUOTRAV®
Number of Participants Analyzed [units: participants]	**57**
Percentage of Subjects Who Reach Target IOP of ≤ 18 mmHg in Subjects Using Ganfort® at Baseline [units: percentage of participants]	
Week 4	**78.6**
Week 12	**85.5**

No statistical analysis provided for Percentage of Subjects Who Reach Target IOP of ≤ 18 mmHg in Subjects Using Ganfort® at Baseline

5. Secondary: Mean Change From Baseline in IOP at Week 4 in Subjects Using Ganfort® at Baseline [Time Frame: Week 4]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in IOP at Week 4 in Subjects Using Ganfort® at Baseline
Measure Description	IOP (fluid pressure in the eye) was measured with Goldmann applanation tonometry. A positive number change from baseline indicates an increase in intraocular pressure, which may be a risk factor for developing glaucoma or glaucoma progression (leading to optic nerve damage). One eye was chosen as the study eye, and only the study eye was used for analysis.
Time Frame	Week 4
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 subjects using Ganfort at baseline who received study medication and attended Week 4 visit.

Reporting Groups

	Description
DUOTRAV®	Travoprost 0.004%+Timolol 0.5% ophthalmic solution, 1 drop to the study eye(s) once a day at 8:00 PM for 12 weeks

Measured Values

	DUOTRAV®
Number of Participants Analyzed [units: participants]	**57**
Mean Change From Baseline in IOP at Week 4 in Subjects Using Ganfort® at Baseline [units: millimeters mercury (mmHg)] Mean (Standard Deviation)	
Baseline (Day 1)	**20.1 (1.1)**
Change from Baseline at Week 4	**-3.8 (2.1)**

No statistical analysis provided for Mean Change From Baseline in IOP at Week 4 in Subjects Using Ganfort® at Baseline

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Adverse events were collected for the duration of the study (1 year, 3 months). An adverse event was defined as any untoward medical occurrence in a subject administered a study treatment regardless of causal relationship.
Additional Description	Adverse events were collected spontaneously from the subjects and systematically by inquiry and review of protocol-specific ocular or systemic parameters evaluated during the study. This reporting group includes all participants who received study medication.

Reporting Groups

	Description
DUOTRAV®	Travoprost 0.004%+Timolol 0.5% ophthalmic solution, 1 drop to the study eye(s) once a day at 8:00 PM for 12 weeks

Serious Adverse Events

	DUOTRAV®
Total, serious adverse events	
# participants affected / at risk	**0/60 (0.00%)**

Other Adverse Events

Hide Other Adverse Events

Time Frame	Adverse events were collected for the duration of the study (1 year, 3 months). An adverse event was defined as any untoward medical occurrence in a subject administered a study treatment regardless of causal relationship.
Additional Description	Adverse events were collected spontaneously from the subjects and systematically by inquiry and review of protocol-specific ocular or systemic parameters evaluated during the study. This reporting group includes all participants who received study medication.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
DUOTRAV®	Travoprost 0.004%+Timolol 0.5% ophthalmic solution, 1 drop to the study eye(s) once a day at 8:00 PM for 12 weeks

Other Adverse Events

	DUOTRAV®
Total, other (not including serious) adverse events	
# participants affected / at risk	**0/60 (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:** France: All results obtained during this study are the property of the Sponsor. All information given to the investigators must remain confidential and cannot be used outside the framework of this study. Germany: Investigators can publish results 12 months after the Sponsor's final evaluation of the data. The Sponsor is entitled to request a delay of such publication due to business or operational reasons.

Results Point of Contact:

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No publications provided

Responsible Party:	Alcon Research
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