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Trial record **1 of 1** for: EMD-06-03

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Adherence Assessment With Travalert Dosing Aid

This study has been completed.

Sponsor:
Alcon Research

Information provided by (Responsible Party):
Alcon Research

ClinicalTrials.gov Identifier:
NCT00508469

First received: July 26, 2007
Last updated: June 8, 2012
Last verified: June 2012
History of Changes

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Results First Received: June 8, 2012

Study Type:	Interventional
Study Design:	Allocation: Randomized; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
Conditions:	Open-angle Glaucoma Ocular Hypertension
Interventions:	Drug: Travoprost 0.004%/timolol 0.5% fixed combination eye drops (DuoTrav) Drug: Travoprost 0.004% eye drops Drug: Timolol 0.05% eye drops Device: Travalert Dosing Aid

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 5 hospitals in Spain.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
Baseline characteristics are presented for the per-protocol population.

Reporting Groups

	Description
Travalert With Travoprost/Timolol Fixed Combination	One drop in the study eye once daily at 9 p.m. for six months using the Travalert device.
Travalert With Travoprost and Timolol	One drop travoprost in the study eye at 9 p.m. and one drop of timolol in the study eye twice daily (9 a.m. and 9 p.m.) for six months using a separate Travalert device for each medication.

Participant Flow: Overall Study

	Travalert With Travoprost/Timolol Fixed Combination	Travalert With Travoprost and Timolol
STARTED	52	50
COMPLETED	35	40
NOT COMPLETED	17	10

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
Travalert With Travoprost/Timolol Fixed Combination	One drop in the study eye once daily at 9 p.m. for six months using the Travalert device.
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Total	Total of all reporting groups

Baseline Measures

	Travalert With Travoprost/Timolol Fixed Combination	Travalert With Travoprost and Timolol	Total
Number of Participants [units: participants]	43	42	85
Age [units: years] Mean (Standard Deviation)	63.8 (11.1)	68.6 (11.8)	66.2 (11.6)
Gender [units: participants]			
Female	26	25	51
Male	17	17	34

Outcome Measures

1. Primary: Adherence [Time Frame: 6 months]

Hide Outcome Measure 1

Measure Type	Primary
Measure Title	Adherence
Measure Description	Patients were considered adherent if a minimum of 80% of their instillations were administered ±2 hours of the scheduled time.
Time Frame	6 months
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

Reporting Groups

	Description
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Measured Values

	Travalert With Travoprost/Timolol Fixed Combination	Travalert With Travoprost and Timolol
Number of Participants Analyzed [units: participants]	**43**	**42**
Adherence [units: percentage of adherent patients]	**63**	**43**

No statistical analysis provided for Adherence

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Adverse events were collected for the duration of the study: 2 years, 3 months.
Additional Description	The safety population includes all enrolled patients.

Reporting Groups

	Description
Travalert With Travoprost/Timolol Fixed Combination	One drop in the study eye once daily at 9 p.m. for six months using the Travalert device.
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Serious Adverse Events

	Travalert With Travoprost/Timolol Fixed Combination	Travalert With Travoprost and Timolol
Total, serious adverse events		
# participants affected / at risk	**1/52 (1.92%)**	**1/50 (2.00%)**
Cardiac disorders		
Heart Failure * 1		
# participants affected / at risk	**1/52 (1.92%)**	**0/50 (0.00%)**
# events	**1**	**0**
Brachycardia * 1		
# participants affected / at risk	**0/52 (0.00%)**	**1/50 (2.00%)**
# events	**0**	**1**

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

Other Adverse Events

Hide Other Adverse Events

Time Frame	Adverse events were collected for the duration of the study: 2 years, 3 months.
Additional Description	The safety population includes all enrolled patients.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
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Other Adverse Events

	Travalert With Travoprost/Timolol Fixed Combination	**Travalert With Travoprost and Timolol**
Total, other (not including serious) adverse events		
# participants affected / at risk	**0/52 (0.00%)**	**0/50 (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: No text entered.

Results Point of Contact:

Name/Title: Severine Durier, PharmD
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No publications provided

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ClinicalTrials.gov Identifier:	NCT00508469 History of Changes
Other Study ID Numbers:	**EMD-06-03**
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Health Authority:	Spain: Ethics Committee