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Trial record **1 of 1** for: EMD-05-03

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Study of Travatan and Cosopt in Primary Open-Angle Glaucoma or Ocular Hypertension

This study has been terminated.

(Question raised by Ethics Committee)

Sponsor:
Alcon Research

Information provided by (Responsible Party):
Alcon Research

ClinicalTrials.gov Identifier:
NCT00471068

First received: May 8, 2007
Last updated: April 7, 2012
Last verified: February 2010
History of Changes

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Results First Received: October 21, 2009

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
Conditions:	Open-angle Glaucoma Ocular Hypertension
Interventions:	Drug: Travatan Drug: Cosopt Drug: Placebo (Timolol Vehicle)

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
Recruitment period: from 13-03-2007 to 30-11-2007 Recruitment restarted on 27-03-2008 to 27-05-2008 First patient first visit: 19-03-2007 Last patient last visit: 29-05-2008

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
After completing the run-in, 8 patients were not randomized: 7 patients did not meet entry criteria and 1 patient was excluded by sponsor's decision.

Reporting Groups

	Description
Travatan	No text entered.
Cosopt	No text entered.

Participant Flow: Overall Study

	Travatan	Cosopt
STARTED	21	25
COMPLETED	20	24
NOT COMPLETED	1	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.
No text entered.

Reporting Groups

	Description
Travatan	No text entered.
Cosopt	No text entered.
Total	Total of all reporting groups

Baseline Measures

	Travatan	Cosopt	Total
Number of Participants [units: participants]	21	25	46
Age [units: participants]			
<=18 years	0	0	0
Between 18 and 65 years	10	16	26
>=65 years	11	9	20
Gender [units: participants]			
Female	14	10	24
Male	7	15	22

Outcome Measures

1. Primary: Intaocular Pressure (IOP) Mean Change After 6 Weeks of Treatment [Time Frame: At week 0 and week 6]

Hide Outcome Measure 1

Measure Type	Primary
Measure Title	Intaocular Pressure (IOP) Mean Change After 6 Weeks of Treatment
Measure Description	IOP measured at week 6 minus IOP measured at baseline
Time Frame	At week 0 and week 6
Safety Issue	Yes

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	No text entered.
Cosopt	No text entered.

Measured Values

	Travatan	Cosopt
Number of Participants Analyzed [units: participants]	**21**	**25**
Intaocular Pressure (IOP) Mean Change After 6 Weeks of Treatment [units: millimeters mercury (mm Hg)] Mean (Standard Deviation)	**-4.57 (1.62)**	**-4.08 (2.50)**

No statistical analysis provided for Intaocular Pressure (IOP) Mean Change After 6 Weeks of Treatment

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Run-in (2-4 weeks) + treatment period (6 weeks)
Additional Description	No text entered.

Reporting Groups

	Description
Travatan	No text entered.
Cosopt	No text entered.

Serious Adverse Events

	Travatan	Cosopt
Total, serious adverse events		
# participants affected / at risk	**0/21 (0.00%)**	**1/25 (4.00%)**
Surgical and medical procedures		
Inguinal hernia surgery [1]		
# participants affected / at risk	**0/21 (0.00%)**	**1/25 (4.00%)**
# events	**0**	**1**

[1] This SAE occurred while patient was in the run-in period taking timolol

Other Adverse Events

Hide Other Adverse Events

Time Frame	Run-in (2-4 weeks) + treatment period (6 weeks)
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	0%

Reporting Groups

	Description
Travatan	No text entered.
Cosopt	No text entered.

Other Adverse Events

	Travatan	Cosopt
Total, other (not including serious) adverse events		
# participants affected / at risk	**2/21 (9.52%)**	**3/25 (12.00%)**
Eye disorders		
Ocular pruritus		
# participants affected / at risk	**1/21 (4.76%)**	**1/25 (4.00%)**
# events	**1**	**1**
Ocular discomfort		
# participants affected / at risk	**0/21 (0.00%)**	**1/25 (4.00%)**
# events	**0**	**1**
Redness eye		
# participants affected / at risk	**1/21 (4.76%)**	**0/25 (0.00%)**
# events	**1**	**0**
Infections and infestations		
Flu		
# participants affected / at risk	**0/21 (0.00%)**	**1/25 (4.00%)**
# events	**0**	**1**

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
Sample size smaller than the one defined by the protocol

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.
There is **NOT** 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.

Results Point of Contact:

Name/Title: Alcon Clinical
Organization: Alcon Labs
phone: 888.451.3937; 817.568.6725
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No publications provided

Responsible Party:	Alcon Research
ClinicalTrials.gov Identifier:	NCT00471068 History of Changes
Other Study ID Numbers:	**EMD-05-03**
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Health Authority:	Infarmed:Portugal