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Trial record **1 of 1** for: IT-04-04

Previous Study | Return to List | Next Study

A Phase IV Study of Travoprost + Brinzolamide to Treat Glaucoma or Ocular Hypertension

This study has been completed.

Sponsor:
Alcon Research

Information provided by:
Alcon Research

ClinicalTrials.gov Identifier:
NCT00471380

First received: May 8, 2007
Last updated: March 10, 2010
Last verified: March 2010
History of Changes

Full Text View | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Results First Received: November 4, 2009

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Crossover Assignment; Masking: Double-Blind; Primary Purpose: Treatment
Conditions:	Glaucoma Ocular Hypertension
Interventions:	Drug: travoprost 0.004% and brinzolamide 1% Drug: fixed combination of timolol 0.5% and dorzolamide 2% plus travoprost 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
46 patients suffering from POAG or ocular hypertension, with an intraocular pressure that was insufficiently controlled were recruited.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
Subjects meeting the inclusion/exclusion criteria were enrolled.

Reporting Groups

	Description
Crossover Group ABB	Participants received Treatment A, which was concomitant administration of travoprost 0.004% (ophthalmic drops, 1 drop/eye at approximately 19:45 p.m.) and brinzolamide 1% (ophthalmic drops, 1 drop/eye, at 08:00 a.m. and at 20:00 p.m.) for period 1 for 8 weeks. Then participants received Treatment B, which was fixed combination of timolol 0.5% and dorzolamide 2% (ophthalmic drops, 1 drop/eye, at 08:00 a.m. and at 20:00 p.m.), and travoprost vehicle (ophthalmic drops, 1 drop/eye, at approximately 19:45 p.m.) for Period 2 (8 weeks) and Period 3 (8 weeks)
Crossover Group BAA	Participants received Treatment B, which was fixed combination of timolol 0.5% and dorzolamide 2% (ophthalmic drops, 1 drop/eye, at 08:00 a.m. and at 20:00 p.m.), and travoprost vehicle (ophthalmic drops, 1 drop/eye, at approximately 19:45 p.m.) for Period 1 (8 weeks). Then participants received Treatment A, which was concomitant administration of travoprost 0.004% (ophthalmic drops, 1 drop/eye at approximately 19:45 p.m.) and brinzolamide

	1% (ophthalmic drops, 1 drop/eye, at 08:00 a.m. and at 20:00 p.m.) for Period 2 (8 weeks) and Period 3 (8 weeks).

Participant Flow for 3 periods

Period 1: First Intervention

	Crossover Group ABB	Crossover Group BAA
STARTED	22	24
COMPLETED	18	20
NOT COMPLETED	4	4

Period 2: Second Intervention

	Crossover Group ABB	Crossover Group BAA
STARTED	18	20
COMPLETED	18	16
NOT COMPLETED	0	4

Period 3: Third Intervention

	Crossover Group ABB	Crossover Group BAA
STARTED	18	16
COMPLETED	17	14
NOT COMPLETED	1	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
Overall Study Population	No text entered.

Baseline Measures

	Overall Study Population
Number of Participants [units: participants]	46
Age [units: participants]	
<=18 years	0
Between 18 and 65 years	23
>=65 years	23
Gender [units: participants]	
Female	28

Male	**18**

Outcome Measures

1. Primary: Intra Ocular Pressure (IOP) [Time Frame: Baseline, end of each period (week 8, week 16, week 24)]

Hide Outcome Measure 1

Measure Type	Primary
Measure Title	Intra Ocular Pressure (IOP)
Measure Description	Intra Ocular Pressure, calculated as AUC (area under the curve) of IOP measured from 8.00 a.m. to 8.00 p.m, at different time-points
Time Frame	Baseline, end of each period (week 8, week 16, week 24)
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
Crossover Group ABB	Participants received Treatment A, which was concomitant administration of travoprost 0.004% (ophthalmic drops, 1 drop/eye at approximately 19:45 p.m.) and brinzolamide 1% (ophthalmic drops, 1 drop/eye, at 08:00 a.m. and at 20:00 p.m.) for period 1 for 8 weeks. Then participants received Treatment B, which was fixed combination of timolol 0.5% and dorzolamide 2% (ophthalmic drops, 1 drop/eye, at 08:00 a.m. and at 20:00 p.m.), and travoprost vehicle (ophthalmic drops, 1 drop/eye, at approximately 19:45 p.m.) for Period 2 (8 weeks) and Period 3 (8 weeks)
Crossover Group BAA	Participants received Treatment B, which was fixed combination of timolol 0.5% and dorzolamide 2% (ophthalmic drops, 1 drop/eye, at 08:00 a.m. and at 20:00 p.m.), and travoprost vehicle (ophthalmic drops, 1 drop/eye, at approximately 19:45 p.m.) for Period 1 (8 weeks). Then participants received Treatment A, which was concomitant administration of travoprost 0.004% (ophthalmic drops, 1 drop/eye at approximately 19:45 p.m.) and brinzolamide 1% (ophthalmic drops, 1 drop/eye, at 08:00 a.m. and at 20:00 p.m.) for Period 2 (8 weeks) and Period 3 (8 weeks).

Measured Values

	Crossover Group ABB	**Crossover Group BAA**
Number of Participants Analyzed [units: participants]	**22**	**24**
Intra Ocular Pressure (IOP) [units: mm Hg (millimeters mercury)*week] Mean (Standard Deviation)		
Week 8	**179.20 (25.42)**	**191.89 (52.59)**
Week 16	**188.82 (32.05)**	**196.26 (59.07)**
Week 24	**201.50 (41.01)**	**191.93 (41.39)**

No statistical analysis provided for Intra Ocular Pressure (IOP)

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	6 Months
Additional Description	No text entered.

Reporting Groups

	Description
Treatment A	Participants received Treatment A, which was concomitant administration of travoprost 0.004% (ophthalmic drops, 1 drop/eye at approximately 19:45 p.m.) and brinzolamide 1% (ophthalmic drops, 1 drop/eye, at 08:00 a.m. and at 20:00 p.m.).
Treatment B	Participants received Treatment B, which was fixed combination of timolol 0.5% and dorzolamide 2% (ophthalmic drops, 1 drop/eye, at 08:00 a.m. and at 20:00 p.m.), and travoprost vehicle (ophthalmic drops, 1 drop/eye, at approximately 19:45 p.m.).

Serious Adverse Events

	Treatment A	Treatment B
Total, serious adverse events		
# participants affected / at risk	**0/22 (0.00%)**	**2/24 (8.33%)**
Injury, poisoning and procedural complications		
Sternal Fracture † 1 [3]		
# participants affected / at risk	**0/22 (0.00%)**	**1/24 (4.17%)**
# events	**0**	**1**
Traumatic Brain Injury † 1 [3]		
# participants affected / at risk	**0/22 (0.00%)**	**1/24 (4.17%)**
# events	**0**	**1**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA dictionary, v
[3] Not drug related

Other Adverse Events

Hide Other Adverse Events

Time Frame	6 Months
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Treatment A	Participants received Treatment A, which was concomitant administration of travoprost 0.004% (ophthalmic drops, 1 drop/eye at approximately 19:45 p.m.) and brinzolamide 1% (ophthalmic drops, 1 drop/eye, at 08:00 a.m. and at 20:00 p.m.).
Treatment B	Participants received Treatment B, which was fixed combination of timolol 0.5% and dorzolamide 2% (ophthalmic drops, 1 drop/eye, at 08:00 a.m. and at 20:00 p.m.), and travoprost vehicle (ophthalmic drops, 1 drop/eye, at approximately 19:45 p.m.).

Other Adverse Events

	Treatment A	Treatment B
Total, other (not including serious) adverse events		
# participants affected / at risk	**11/22 (50.00%)**	**3/24 (12.50%)**

Eye disorders		
Conjunctivitis Allergic † 1		
# participants affected / at risk	**3/22 (13.64%)**	**1/24 (4.17%)**
# events	**3**	**1**
Eye Irritation † 1		
# participants affected / at risk	**8/22 (36.36%)**	**2/24 (8.33%)**
# events	**8**	**2**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA dictionary, v

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:** Any formal presentation of data publication from this study has to be a joint presentation from both the Investigators and the Sponsor. Being the study multicentric, it is mandatory that the first publication is based on data from all the centres, analysed according to the protocol. Data from a single Centre can not be presented, unless there Is a formal agreement from the other Investigators and Alcon.

Results Point of Contact:

Name/Title: Alcon Clinical
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No publications provided

ClinicalTrials.gov Identifier: NCT00471380 History of Changes
Other Study ID Numbers: **IT-04-04**
EudraCT 200600362737
Study First Received: May 8, 2007
Results First Received: November 4, 2009

Last Updated:	March 10, 2010
Health Authority:	Agenzua Italiana del Farmaco: Italy