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Trial record **1 of 1** for: RDG-10-246

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Safety and Efficacy of Adding AZARGA® Adjunctive to Prostaglandin Therapy

This study has been completed.

Sponsor:
Alcon Research

Information provided by (Responsible Party):
Alcon Research

ClinicalTrials.gov Identifier:
NCT01263444

First received: December 17, 2010
Last updated: May 18, 2014
Last verified: May 2014
History of Changes

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Results First Received: April 23, 2014

Study Type:	Interventional
Study Design:	Intervention Model: Single Group Assignment; Masking: Open Label; Primary Purpose: Treatment
Conditions:	Glaucoma Ocular Hypertension
Interventions:	Drug: Brinzolamide 1% / timolol 0.5% Fixed Combination Drug: Habitual prostaglandin monotherapy

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 3 study centers located in Austria and 2 study centers located in Spain.

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 (47).

Reporting Groups

	Description
Azarga	Brinzolamide 1% / timolol 0.5% Fixed Combination administered as 1 drop in study eye(s) twice a day (8:00 AM and 8:00 PM) for 12 weeks, at a 5 minute interval from the habitual prostaglandin monotherapy.

Participant Flow: Overall Study

	Azarga
STARTED	**47**
COMPLETED	**37**
NOT COMPLETED	**10**

Adverse Event	**8**
Withdrawal by Subject	**1**
Protocol Violation	**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 analysis population includes all enrolled participants.

Reporting Groups

	Description
Azarga	Brinzolamide 1% / timolol 0.5% Fixed Combination administered as 1 drop in study eye(s) twice a day (8:00 AM and 8:00 PM) for 12 weeks, at a 5 minute interval from the habitual prostaglandin monotherapy.

Baseline Measures

	Azarga
Number of Participants [units: participants]	**47**
Age, Customized [units: participants]	
≤55 Years	**3**
56-65 Years	**10**
66-75 Years	**25**
≥ 76 Years	**9**
Gender [units: participants]	
Female	**24**
Male	**23**

Outcome Measures

Hide All Outcome Measures

1. Primary: Mean Change From Baseline in Intraocular Pressure (IOP) at Week 12 [Time Frame: Baseline, Week 12]

Measure Type	Primary
Measure Title	Mean Change From Baseline in Intraocular Pressure (IOP) at Week 12
Measure Description	IOP (fluid pressure inside the eye) was measured by Goldmann applanation tonometry. A higher IOP can be a greater risk for developing glaucoma or glaucoma progression (leading to optic nerve damage). A more negative change indicates a greater amount of improvement. Only one eye (study eye) contributed to the mean.
Time Frame	Baseline, 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.
This analysis population includes all patients who received study medication and had at least one on-therapy study visit minus missing responses and/or visit attendance.

Reporting Groups

	Description
Azarga	Brinzolamide 1% / timolol 0.5% Fixed Combination administered as 1 drop in study eye(s) twice a day (8:00 AM and 8:00 PM) for 12 weeks, at a 5 minute interval from the habitual prostaglandin monotherapy.

Measured Values

	Azarga
Number of Participants Analyzed [units: participants]	**47**
Mean Change From Baseline in Intraocular Pressure (IOP) at Week 12 [units: mmHg] Mean (Standard Deviation)	**-6.0 (3.2)**

No statistical analysis provided for Mean Change From Baseline in Intraocular Pressure (IOP) at Week 12

2. Secondary: Mean Change From Baseline in IOP Per Prostaglandin Group at Week 12 [Time Frame: Baseline, Week 12]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in IOP Per Prostaglandin Group at Week 12
Measure Description	IOP (fluid pressure inside the eye) was measured by Goldmann applanation tonometry. A higher IOP can be a greater risk for developing glaucoma or glaucoma progression (leading to optic nerve damage). A more negative change indicates a greater amount of improvement. Only prostaglandin subgroups with ≥ 15 patients were analyzed. Only one eye (study eye) contributed to the mean.
Time Frame	Baseline, 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.
This analysis population includes all patients who received study medication and had at least one on-therapy study visit minus missing responses and/or visit attendance.

Reporting Groups

	Description
Azarga	Brinzolamide 1% / timolol 0.5% Fixed Combination administered as 1 drop in study eye(s) twice a day (8:00 AM and 8:00 PM) for 12 weeks, at a 5 minute interval from the habitual prostaglandin monotherapy.

Measured Values

	Azarga
Number of Participants Analyzed [units: participants]	**47**
Mean Change From Baseline in IOP Per Prostaglandin Group at Week 12 [units: mmHg] Mean (Standard Deviation)	
AZARGA + Latanoprost (n=22)	**-7.1 (2.9)**

AZARGA + Travoprost (n=15)	**-5.1 (3.4)**

No statistical analysis provided for Mean Change From Baseline in IOP Per Prostaglandin Group at Week 12

3. Secondary: Mean Change From Baseline in IOP at Week 4 [Time Frame: Baseline, Week 4]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in IOP at Week 4
Measure Description	IOP (fluid pressure inside the eye) was measured by Goldmann applanation tonometry. A higher IOP can be a greater risk for developing glaucoma or glaucoma progression (leading to optic nerve damage). A more negative change indicates a greater amount of improvement. Only one eye (study eye) contributed to the mean.
Time Frame	Baseline, 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.
This analysis population includes all patients who received study medication and had at least one on-therapy study visit minus missing responses and/or visit attendance.

Reporting Groups

	Description
Azarga	Brinzolamide 1% / timolol 0.5% Fixed Combination administered as 1 drop in study eye(s) twice a day (8:00 AM and 8:00 PM) for 12 weeks, at a 5 minute interval from the habitual prostaglandin monotherapy.

Measured Values

	Azarga
Number of Participants Analyzed [units: participants]	**47**
Mean Change From Baseline in IOP at Week 4 [units: mmHg] Mean (Standard Deviation)	**-6.0 (3.2)**

No statistical analysis provided for Mean Change From Baseline in IOP at Week 4

4. Secondary: Percentage of Patients Reaching the Target IOP (≤ 18 mmHg) [Time Frame: Week 12]

Measure Type	Secondary
Measure Title	Percentage of Patients Reaching the Target IOP (≤ 18 mmHg)
Measure Description	IOP (fluid pressure inside the eye) was assessed using Goldmann applanation tonometry and measured in millimeters of mercury (mmHg). A higher IOP can be a greater risk factor for developing glaucoma or glaucoma progression (leading to optic nerve damage). Only one eye (study eye) was assessed.
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.

This analysis population includes all patients who received study medication and had at least one on-therapy study visit minus missing responses and/or visit attendance.

Reporting Groups

	Description
Azarga	Brinzolamide 1% / timolol 0.5% Fixed Combination administered as 1 drop in study eye(s) twice a day (8:00 AM and 8:00 PM) for 12 weeks, at a 5 minute interval from the habitual prostaglandin monotherapy.

Measured Values

	Azarga
Number of Participants Analyzed [units: participants]	**47**
Percentage of Patients Reaching the Target IOP (≤ 18 mmHg) [units: percentage of participants]	**70.0**

No statistical analysis provided for Percentage of Patients Reaching the Target IOP (≤ 18 mmHg)

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Adverse events (AEs) were collected for the duration of the study (2 years, 1 month). This analysis group includes all patients who received study medication.
Additional Description	An AE was defined as any untoward medical occurrence in a patient who is administered a study treatment, regardless of causal relationship with the treatment. Reports of AEs were obtained through solicited and spontaneous comments from the patients and through observations by the Investigator as outlined in the study protocol.

Reporting Groups

	Description
Azarga	Brinzolamide 1% / timolol 0.5% Fixed Combination administered as 1 drop in study eye(s) twice a day (8:00 AM and 8:00 PM) for 12 weeks, at a 5 minute interval from the habitual prostaglandin monotherapy.

Serious Adverse Events

	Azarga
Total, serious adverse events	
# participants affected / at risk	**1/47 (2.13%)**
General disorders	
Pseudo stenocardia *	
# participants affected / at risk	**1/47 (2.13%)**

* Events were collected by non-systematic assessment

Other Adverse Events

Hide Other Adverse Events

Time Frame	Adverse events (AEs) were collected for the duration of the study (2 years, 1 month). This analysis group includes all patients who received study medication.
Additional Description	An AE was defined as any untoward medical occurrence in a patient who is administered a study treatment,

	regardless of causal relationship with the treatment. Reports of AEs were obtained through solicited and spontaneous comments from the patients and through observations by the Investigator as outlined in the study protocol.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Azarga	Brinzolamide 1% / timolol 0.5% Fixed Combination administered as 1 drop in study eye(s) twice a day (8:00 AM and 8:00 PM) for 12 weeks, at a 5 minute interval from the habitual prostaglandin monotherapy.

Other Adverse Events

	Azarga
Total, other (not including serious) adverse events	
# participants affected / at risk	**0/47 (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
A single-arm, non-randomized study somewhat limits interpretation of efficacy results. A 3-month duration does not allow for long-term safety conclusions; however, data obtained at V2 and V3 did not vary much, indicating a steady state at Month 1.

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:** Sponsor reserves the right of prior review of any publication or presentation of information related to the study.

Results Point of Contact:

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No publications provided

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