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Trial record **1 of 1** for: RDG-10-251

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Patient Preference Comparison of AZARGA Versus COSOPT

This study has been completed.

Sponsor:
Alcon Research

Information provided by (Responsible Party):
Alcon Research

ClinicalTrials.gov Identifier:
NCT01340014

First received: April 20, 2011
Last updated: January 13, 2014
Last verified: January 2014
History of Changes

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Results First Received: October 18, 2013

Study Type:	Interventional
Study Design:	Allocation: Randomized; Intervention Model: Crossover Assignment; Masking: Single Blind (Subject); Primary Purpose: Treatment
Conditions:	Open-Angle Glaucoma Ocular Hypertension
Interventions:	Drug: Brinzolamide 1.0% + Timolol 0.5% ophthalmic suspension Drug: Dorzolamide 2.0% + 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 11 study centers located in Europe.

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 as treated.

Reporting Groups

	Description
AZARGA/COSOPT	1 drop AZARGA instilled in each eye twice a day for 7 days during Period 1, followed by 1 drop COSOPT instilled in each eye twice a day for 7 days during Period 2. A 48-hour washout period separated the two treatment periods.
COSOPT/AZARGA	1 drop COSOPT instilled in each eye twice a day for 7 days during Period 1, followed by 1 drop AZARGA instilled in each eye twice a day for 7 days during Period 2. A 48-hour washout period separated the two treatment periods.

Participant Flow for 2 periods

Period 1: Period 1, First 7 Days

	AZARGA/COSOPT	COSOPT/AZARGA

STARTED	**55**	**57**
COMPLETED	**53**	**57**
NOT COMPLETED	**2**	**0**
Adverse Event	**1**	**0**
Personal Reasons	**1**	**0**

Period 2: Period 2, Second 7 Days

	AZARGA/COSOPT	COSOPT/AZARGA
STARTED	**53**	**57**
COMPLETED	**53**	**56**
NOT COMPLETED	**0**	**1**
Adverse Event	**0**	**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 completed both treatment periods and completed the preference questionnaire, per planned treatment sequence (ITT full analysis population).

Reporting Groups

	Description
AZARGA/COSOPT	1 drop AZARGA instilled in each eye twice a day for 7 days during Period 1, followed by 1 drop COSOPT instilled in each eye twice a day for 7 days during Period 2. A 48-hour washout period separated the two treatment periods.
COSOPT/AZARGA	1 drop COSOPT instilled in each eye twice a day for 7 days during Period 1, followed by 1 drop AZARGA instilled in each eye twice a day for 7 days during Period 2. A 48-hour washout period separated the two treatment periods.
Total	Total of all reporting groups

Baseline Measures

	AZARGA/COSOPT	COSOPT/AZARGA	Total
Number of Participants [units: participants]	**54**	**54**	**108**
Age [units: years] Mean (Standard Deviation)	**67.7 (10.1)**	**65.0 (11.92)**	**66.3 (11.40)**
Gender [units: participants]			
Female	**38**	**31**	**69**
Male	**16**	**23**	**39**

Outcome Measures

Hide All Outcome Measures

1. Primary: Preferred Treatment [Time Frame: At the end of both periods, Day 15]

Measure Type	Primary
Measure Title	Preferred Treatment
Measure Description	The participant completed a questionnaire on the Day 15 visit (ie, after administration of both study medications) consisting of a single preference question: "Thinking about the comfort of the two medications (1st and 2nd) that you took during this study, which medication do you prefer?" Preferred treatment is presented as a percentage.
Time Frame	At the end of both periods, Day 15
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 reporting group includes all participants who completed both treatment periods and completed the preference questionnaire, as treated.

Reporting Groups

	Description
AZARGA	1 drop AZARGA instilled in each eye twice a day for 7 days during Period 1 or Period 2
COSOPT	1 drop COSOPT instilled in each eye twice a day for 7 days during Period 1 or Period 2

Measured Values

	AZARGA	COSOPT
Number of Participants Analyzed [units: participants]	**108**	**108**
Preferred Treatment [units: Percentage of participants]	**60.2**	**39.8**

No statistical analysis provided for Preferred Treatment

2. Secondary: Ocular Discomfort [Time Frame: Day 7 of each period]

Measure Type	Secondary
Measure Title	Ocular Discomfort
Measure Description	Ocular discomfort was assessed by the participant 1 minute after instillation of the study medication. Ocular discomfort was rated on a 10-point scale (0=no discomfort, 9=substantial discomfort).
Time Frame	Day 7 of each period
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 reporting group includes all participants who completed both treatment periods and completed the preference questionnaire, as treated, minus any missing responses.

Reporting Groups

	Description
AZARGA	1 drop AZARGA instilled in each eye twice a day for 7 days during Period 1 or Period 2
COSOPT	1 drop COSOPT instilled in each eye twice a day for 7 days during Period 1 or Period 2

Measured Values

	AZARGA	COSOPT
Number of Participants Analyzed [units: participants]	**108**	**108**
Ocular Discomfort [units: Units on a scale] Mean (Standard Deviation)	**2.6 (2.27)**	**3.7 (2.63)**

No statistical analysis provided for Ocular Discomfort

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Adverse events were collected for the duration of the study (September 2011 to October 2012). An adverse event was defined as any untoward medical condition in a subject administered a study treatment regardless of causal relationship.
Additional Description	This reporting group includes all participants who received at least one dose of study medication. At each visit the Investigator inquired about adverse events by asking the standard question, "Have you had any health problems since your last study visit?"

Reporting Groups

	Description
AZARGA	1 drop AZARGA instilled in each eye twice a day for 7 days during Period 1 or Period 2
COSOPT	1 drop COSOPT instilled in each eye twice a day for 7 days during Period 1 or Period 2

Serious Adverse Events

	AZARGA	COSOPT
Total, serious adverse events		
# participants affected / at risk	**0/112 (0.00%)**	**0/112 (0.00%)**

Other Adverse Events

Hide Other Adverse Events

Time Frame	Adverse events were collected for the duration of the study (September 2011 to October 2012). An adverse event was defined as any untoward medical condition in a subject administered a study treatment regardless of causal relationship.
Additional Description	This reporting group includes all participants who received at least one dose of study medication. At each visit the Investigator inquired about adverse events by asking the standard question, "Have you had any health problems since your last study visit?"

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
AZARGA	1 drop AZARGA instilled in each eye twice a day for 7 days during Period 1 or Period 2

COSOPT	1 drop COSOPT instilled in each eye twice a day for 7 days during Period 1 or Period 2

Other Adverse Events

	AZARGA	COSOPT
Total, other (not including serious) adverse events		
# participants affected / at risk	**0/112 (0.00%)**	**0/112 (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: 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

Responsible Party:	Alcon Research
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