ClinicalTrials.gov
A service of the U.S. National Institutes of Health

Trial record **1 of 1** for: NCT00800540
Previous Study | Return to List | Next Study

Circadian Ocular Perfusion Pressure and Ocular Blood Flow

This study has been completed.

Sponsor:
Alcon Research

Information provided by (Responsible Party):
Alcon Research

ClinicalTrials.gov Identifier:
NCT00800540

First received: December 1, 2008
Last updated: March 20, 2013
Last verified: March 2013
History of Changes

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

Results First Received: January 31, 2013

Study Type:	Interventional
Study Design:	Allocation: Randomized; Intervention Model: Crossover Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
Condition:	Glaucoma
Interventions:	Drug: Brinzolamide 10 mg/ml/Timolol 5 mg/ml eye drops suspension Drug: Brimonidine 20 mg/ml/Timolol 5 mg/ml eye drops 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 and enrolled at one study center located in Greece.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
No text entered.

Reporting Groups

	Description
AZARGA/COMBIGAN	AZARGA, followed by COMBIGAN, as randomized. Each fixed combination was used for 6 weeks, with a 4-week washout period separating the two treatment periods.
COMBIGAN/AZARGA	COMBIGAN, followed by AZARGA, as randomized. Each fixed combination was used for 6 weeks, with a 4-week washout period separating the two treatment periods.

Participant Flow for 3 periods

Period 1: Period One: 6 Weeks

	AZARGA/COMBIGAN	COMBIGAN/AZARGA
STARTED	**17**	**18**

COMPLETED	**16**	**17**
NOT COMPLETED	**1**	**1**
Noncompliance	**1**	**0**
Pt Decision Unrelated to Adverse Event	**0**	**1**

Period 2: Washout: 4 Weeks

	AZARGA/COMBIGAN	COMBIGAN/AZARGA
STARTED	**16**	**17**
COMPLETED	**16**	**17**
NOT COMPLETED	**0**	**0**

Period 3: Period 2: 6 Weeks

	AZARGA/COMBIGAN	COMBIGAN/AZARGA
STARTED	**16**	**17**
COMPLETED	**16**	**16**
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 enrolled participants.

Reporting Groups

	Description
Overall	All enrolled

Baseline Measures

	Overall
Number of Participants [units: participants]	**35**
Age [units: years] Mean (Standard Deviation)	**65.2 (10.3)**
Gender [units: participants]	
Female	**19**
Male	**16**
Region of Enrollment [units: participants]	
Greece	**35**

Outcome Measures

Hide All Outcome Measures

1. Primary: Mean Change From Baseline in Overall Diastolic Ocular Perfusion Pressure at Week 6 [Time Frame: Week 0, Week 6 (period-based)]

Measure Type	Primary
Measure Title	Mean Change From Baseline in Overall Diastolic Ocular Perfusion Pressure at Week 6
Measure Description	Diastolic ocular perfusion pressure (DOPP) is defined as the difference between diastolic arterial pressure and intraocular pressure. Diastolic arterial pressure was measured with a calibrated automated sphygmomanometer. Intraocular pressure was measured with a calibrated pneumatonometer. A lower DOPP indicates a lower optic blood supply, which can be a risk factor for developing glaucoma or glaucoma progression (leading to optic nerve damage).
Time Frame	Week 0, Week 6 (period-based)
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 patients who received study medication and completed the on-therapy follow-up study visit in both periods (ITT).

Reporting Groups

	Description
AZARGA	One drop in the study eye, twice daily (9:00 and 21:00), for six weeks
COMBIGAN	One drop in the study eye, twice daily (9:00 and 21:00), for six weeks

Measured Values

	AZARGA	**COMBIGAN**
Number of Participants Analyzed [units: participants]	**32**	**32**
Number of eyes Analyzed [units: eyes]	**41**	**41**
Mean Change From Baseline in Overall Diastolic Ocular Perfusion Pressure at Week 6 [units: mmHg (millimeters of mercury)] Mean (Standard Error)	**2.6 (0.780)**	**0.8 (0.779)**

No statistical analysis provided for Mean Change From Baseline in Overall Diastolic Ocular Perfusion Pressure at Week 6

2. Secondary: Mean Change From Baseline in Circadian Diastolic Ocular Perfusion Pressure at Week 6 [Time Frame: Week 0, Week 6 (period-based)]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in Circadian Diastolic Ocular Perfusion Pressure at Week 6
Measure Description	Circadian diastolic ocular perfusion pressure (COPP) is defined as the variations in diastolic OPP during the day and night. Diastolic ocular perfusion pressure was calculated at 7 timepoints over a 24-hour period. Changes in the diastolic ocular perfusion pressure rhythm throughout the day (outside the normal range) may affect glaucoma progression.
Time Frame	Week 0, Week 6 (period-based)
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 patients who received study medication and completed the on-therapy follow-up study visit in both periods (ITT).

Reporting Groups

	Description
AZARGA	One drop in the study eye, twice daily (9:00 and 21:00), for six weeks
COMBIGAN	One drop in the study eye, twice daily (9:00 and 21:00), for six weeks

Measured Values

	AZARGA	**COMBIGAN**
Number of Participants Analyzed [units: participants]	**32**	**32**
Number of eyes Analyzed [units: eyes]	**41**	**41**
Mean Change From Baseline in Circadian Diastolic Ocular Perfusion Pressure at Week 6 [units: mmHg (millimeters of mercury)] Mean (Standard Error)		
9:00 am	**2.8 (1.282)**	**6.5 (1.282)**
1:00 pm	**3.0 (1.282)**	**2.1 (1.282)**
5:00 pm	**4.4 (1.282)**	**3.9 (1.282)**
9:00 pm	**4.5 (1.282)**	**2.0 (1.282)**
12:00 am	**0.8 (1.282)**	**-5.6 (1.282)**
3:00 am	**0.3 (1.282)**	**-4.0 (1.282)**
6:00 am	**2.0 (1.296)**	**0.9 (1.282)**

No statistical analysis provided for Mean Change From Baseline in Circadian Diastolic Ocular Perfusion Pressure at Week 6

3. Secondary: Mean Change From Baseline in Mean Flow Value in the Superotemporal Peripapillary Retina at Week 6 [Time Frame: Week 0, Week 6 (period-based)]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in Mean Flow Value in the Superotemporal Peripapillary Retina at Week 6
Measure Description	Retinal perfusion assessments were made using Heidelberg Retinal Flowmetry (HRF). Assessments were made at 4 timepoints over a 12-hour period. Intensity of blood flow was measured in arbitrary units, with a higher number indicating an increased blood flow. An increase in ocular blood flow may reduce the risk of glaucoma progression.
Time Frame	Week 0, Week 6 (period-based)
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 patients who received study medication and completed the on-therapy follow-up study visit in both periods (ITT). The analysis is based on patient eye-matched image data received.

Reporting Groups

	Description
AZARGA	One drop in the study eye, twice daily (9:00 and 21:00), for six weeks
COMBIGAN	One drop in the study eye, twice daily (9:00 and 21:00), for six weeks

Measured Values

	AZARGA	COMBIGAN
Number of Participants Analyzed [units: participants]	**32**	**32**
Number of eyes Analyzed [units: eyes]	**41**	**41**
Mean Change From Baseline in Mean Flow Value in the Superotemporal Peripapillary Retina at Week 6 [units: Arbitrary Units] Mean (Standard Error)		
9:00 am	**-272.4 (146.294)**	**-43.5 (146.586)**
1:00 pm	**-12.1 (142.844)**	**248.9 (144.917)**
5:00 pm	**-26.7 (144.914)**	**-51.3 (142.844)**
9:00 pm	**14.0 (148.317)**	**-33.2 (144.451)**

No statistical analysis provided for Mean Change From Baseline in Mean Flow Value in the Superotemporal Peripapillary Retina at Week 6

4. Secondary: Mean Change From Baseline in Mean Flow Value in the Inverotemporal Peripapillary Retina at Week 6 [Time Frame: Week 0, Week 6 (period-based)]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in Mean Flow Value in the Inverotemporal Peripapillary Retina at Week 6
Measure Description	Retinal perfusion assessments were made using Heidelberg Retinal Flowmetry (HRF). Assessments were made at 4 timepoints over a 12-hour period. Intensity of blood flow was measured in arbitrary units, with a higher number indicating an increased blood flow. An increase in ocular blood flow may reduce the risk of glaucoma progression.
Time Frame	Week 0, Week 6 (period-based)
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 patients who received study medication and completed the on-therapy follow-up study visit in both periods (ITT). The analysis is based on patient eye-matched image data received.

Reporting Groups

	Description
AZARGA	One drop in the study eye, twice daily (9:00 and 21:00), for six weeks
COMBIGAN	One drop in the study eye, twice daily (9:00 and 21:00), for six weeks

Measured Values

	AZARGA	COMBIGAN

Number of Participants Analyzed [units: participants]	**32**	**32**
Number of eyes Analyzed [units: eyes]	**41**	**41**
Mean Change From Baseline in Mean Flow Value in the Inverotemporal Peripapillary Retina at Week 6 [units: Arbitrary Units] Mean (Standard Error)		
9:00 am	**15.9 (92.064)**	**-70.0 (89.642)**
1:00 pm	**-40.7 (89.642)**	**-89.2 (95.324)**
5:00 pm	**-38.7 (88.363)**	**-69.1 (92.610)**
9:00 pm	**182.3 (92.064)**	**-91.0 (92.064)**

No statistical analysis provided for Mean Change From Baseline in Mean Flow Value in the Inverotemporal Peripapillary Retina at Week 6

5. Secondary: Mean Change From Baseline in Intraocular Pressure (IOP) at Week 6 [Time Frame: Week 0, Week 6 (period-based)]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in Intraocular Pressure (IOP) at Week 6
Measure Description	Intraocular pressure (IOP) is defined as the fluid pressure inside the eye. Intraocular pressure was measured with a calibrated pneumatonometer at 7 time points over a 24-hour period. High IOP (outside the normal range) can be a risk factor for developing glaucoma or glaucoma progression (leading to optic nerve damage).
Time Frame	Week 0, Week 6 (period-based)
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 patients who received study medication and completed the on-therapy follow-up study visit in both periods (ITT).

Reporting Groups

	Description
AZARGA	One drop in the study eye, twice daily (9:00 and 21:00), for six weeks
COMBIGAN	One drop in the study eye, twice daily (9:00 and 21:00), for six weeks

Measured Values

	AZARGA	**COMBIGAN**
Number of Participants Analyzed [units: participants]	**32**	**32**
Number of eyes Analyzed [units: eyes]	**41**	**41**
Mean Change From Baseline in Intraocular Pressure (IOP) at Week 6 [units: mmHg (millimeters of mercury)] Mean (Standard Error)		
9:00 am	**-6.3 (0.661)**	**-6.5 (0.661)**
1:00 pm	**-6.0 (0.661)**	**-6.5 (0.661)**
5:00 pm	**-5.6 (0.661)**	**-5.2 (0.661)**

9:00 pm	**-4.3 (0.661)**	**-4.9 (0.661)**
12:00 am	**-1.9 (0.661)**	**-1.6 (0.661)**
3:00 am	**-1.3 (0.661)**	**-0.6 (0.661)**
6:00 am	**-2.3 (0.668)**	**-1.2 (0.661)**

No statistical analysis provided for Mean Change From Baseline in Intraocular Pressure (IOP) at Week 6

6. Secondary: Mean Change From Baseline in Diastolic Blood Pressure at Week 6 [Time Frame: Week 0, Week 6 (period-based)]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in Diastolic Blood Pressure at Week 6
Measure Description	Blood pressure is defined as the pressure exerted by circulating blood upon the walls of the blood vessels, that is, arterial pressure of the systemic circulation of blood. Diastolic blood pressure refers to the minimum pressure, that is, the pressure between heartbeats. Diastolic glood pressure was measured at 7 timepoints in a 24-hour period using a calibrated sphygmomonometer. Higher blood pressure (outside the normal range) can be a risk factor for developing cardiovascular events, such as heart attack, stroke, or heart failure. Lower blood pressure (outside the normal range) can be a risk factor for dizziness or fainting.
Time Frame	Week 0, Week 6 (period-based)
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 patients who received study medication and completed the on-therapy follow-up study visit in both periods (ITT).

Reporting Groups

	Description
AZARGA	One drop in the study eye, twice daily (9:00 and 21:00), for six weeks
COMBIGAN	One drop in the study eye, twice daily (9:00 and 21:00), for six weeks

Measured Values

	AZARGA	**COMBIGAN**
Number of Participants Analyzed [units: participants]	**32**	**32**
Mean Change From Baseline in Diastolic Blood Pressure at Week 6 [units: mmHg (millimeters of mercury)] Mean (Standard Error)		
9:00 am	**-3.3 (1.315)**	**0.6 (1.315)**
1:00 pm	**-3.5 (1.315)**	**-4.3 (1.315)**
5:00 pm	**-1.5 (1.315)**	**-0.9 (1.315)**
9:00 pm	**-0.5 (1.315)**	**-2.1 (1.315)**
12:00 am	**-1.4 (1.315)**	**-7.3 (1.315)**
3:00 am	**-1.5 (1.315)**	**-3.8 (1.315)**
6:00 am	**-0.5 (1.334)**	**-0.7 (1.315)**

No statistical analysis provided for Mean Change From Baseline in Diastolic Blood Pressure at Week 6

7. Secondary: Mean Change From Baseline in Systolic Blood Pressure at Week 6 [Time Frame: Week 0, Week 6 (period-based)]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in Systolic Blood Pressure at Week 6
Measure Description	Blood pressure is defined as the pressure exerted by circulating blood upon the walls of the blood vessels, that is, arterial pressure of the systemic circulation of blood. Systolic blood pressure refers to the maximum pressure, that is, the pressure while the heart is beating, and was measured at 7 timepoints in a 24-hour period using a calibrated sphygmomonometer. Higher blood pressure (outside the normal range) can be a risk factor for developing cardiovascular events, such as heart attack, stroke, or heart failure. Lower blood pressure (outside the normal range) can be a risk factor for dizziness or fainting.
Time Frame	Week 0, Week 6 (period-based)
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 patients who received study medication and completed the on-therapy follow-up study visit in both periods (ITT).

Reporting Groups

	Description
AZARGA	One drop in the study eye, twice daily (9:00 and 21:00), for six weeks
COMBIGAN	One drop in the study eye, twice daily (9:00 and 21:00), for six weeks

Measured Values

	AZARGA	COMBIGAN
Number of Participants Analyzed [units: participants]	**32**	**32**
Mean Change From Baseline in Systolic Blood Pressure at Week 6 [units: mmHg (millimeters of mercury)] Mean (Standard Error)		
9:00 am	**-4.2 (2.134)**	**4.5 (2.134)**
1:00 pm	**-2.6 (2.134)**	**-1.9 (2.134)**
5:00 pm	**-2.9 (2.134)**	**-0.4 (2.134)**
9:00 pm	**-1.4 (2.134)**	**-0.6 (2.134)**
12:00 am	**-2.9 (2.134)**	**-12.2 (2.134)**
3:00 am	**-2.9 (2.134)**	**-3.0 (2.134)**
6:00 am	**-0.1 (2.165)**	**3.0 (2.134)**

No statistical analysis provided for Mean Change From Baseline in Systolic Blood Pressure at Week 6

8. Secondary: Mean Change From Baseline in Vascular Resistance in the Central Retinal Artery at Week 6 [Time Frame: Week 0, Week 6 (period-based)]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in Vascular Resistance in the Central Retinal Artery at Week 6

Measure Description	Vascular resistance in the central retinal artery was assessed using Color Doppler Imaging (CDI). Assessments were made at 7 time points over a 24-hour period.
Time Frame	Week 0, Week 6 (period-based)
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 patients who received study medication and completed the on-therapy follow-up study visit in both periods (ITT). The analysis is based on patient eye-matched image data received.

Reporting Groups

	Description
AZARGA	One drop in the study eye, twice daily (9:00 and 21:00), for six weeks
COMBIGAN	One drop in the study eye, twice daily (9:00 and 21:00), for six weeks

Measured Values

	AZARGA	COMBIGAN
Number of Participants Analyzed [units: participants]	**32**	**32**
Number of eyes Analyzed [units: eyes]	**41**	**41**
Mean Change From Baseline in Vascular Resistance in the Central Retinal Artery at Week 6 [units: cm/s (centimeters per second)] Mean (Standard Error)		
9:00 am	**-0.00 (0.014)**	**0.01 (0.014)**
1:00 pm	**-0.01 (0.014)**	**0.01 (0.014)**
5:00 pm	**0.00 (0.014)**	**-0.00 (0.014)**
9:00 pm	**0.00 (0.014)**	**0.02 (0.014)**
12:00 am	**0.02 (0.014)**	**-0.01 (0.014)**
3:00 am	**0.01 (0.014)**	**0.01 (0.014)**
6:00 am	**-0.02 (0.014)**	**0.02 (0.014)**

No statistical analysis provided for Mean Change From Baseline in Vascular Resistance in the Central Retinal Artery at Week 6

9. Secondary: Mean Change From Baseline in Vascular Resistance in the Ophthalmic Artery at 6 Weeks [Time Frame: Week 0, Week 6 (period-based)]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in Vascular Resistance in the Ophthalmic Artery at 6 Weeks
Measure Description	Vascular resistance in the ophthalmic artery was assessed using Color Doppler Imaging (CDI). Assessments were made at 7 time points over a 24-hour period.
Time Frame	Week 0, Week 6 (period-based)
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 patients who received study medication and completed the on-therapy follow-up study visit in both periods (ITT). The analysis is based on patient eye-matched image data received.

Reporting Groups

	Description
AZARGA	One drop in the study eye, twice daily (9:00 and 21:00), for six weeks
COMBIGAN	One drop in the study eye, twice daily (9:00 and 21:00), for six weeks

Measured Values

	AZARGA	**COMBIGAN**
Number of Participants Analyzed [units: participants]	**32**	**32**
Number of eyes Analyzed [units: eyes]	**41**	**41**
Mean Change From Baseline in Vascular Resistance in the Ophthalmic Artery at 6 Weeks [units: cm/s (centimeters per second)] Mean (Standard Error)		
9:00 am	**-0.01 (0.012)**	**-0.01 (0.011)**
1:00 pm	**0.02 (0.012)**	**0.02 (0.012)**
5:00 pm	**0.01 (0.012)**	**0.01 (0.012)**
9:00 pm	**0.01 (0.012)**	**0.01 (0.011)**
12:00 am	**-0.01 (0.012)**	**0.02 (0.012)**
3:00 am	**0.01 (0.012)**	**0.03 (0.012)**
6:00 am	**0.01 (0.012)**	**0.03 (0.011)**

No statistical analysis provided for Mean Change From Baseline in Vascular Resistance in the Ophthalmic Artery at 6 Weeks

10. Secondary: Mean Change From Baseline in End Diastolic Velocity in the Ophthalmic Artery at Week 6 [Time Frame: Week 0, Week 6 (period-based)]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in End Diastolic Velocity in the Ophthalmic Artery at Week 6
Measure Description	End diastolic velocity in the ophthalmic artery was assessed using Color Doppler Imaging (CDI). Assessments were made at 7 time points over a 24-hour period.
Time Frame	Week 0, Week 6 (period-based)
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 patients who received study medication and completed the on-therapy follow-up study visit in both periods (ITT). The analysis is based on patient eye-matched image data received.

Reporting Groups

	Description
AZARGA	One drop in the study eye, twice daily (9:00 and 21:00), for six weeks

COMBIGAN	One drop in the study eye, twice daily (9:00 and 21:00), for six weeks

Measured Values

	AZARGA	COMBIGAN
Number of Participants Analyzed [units: participants]	**32**	**32**
Number of eyes Analyzed [units: eyes]	**41**	**41**
Mean Change From Baseline in End Diastolic Velocity in the Ophthalmic Artery at Week 6 [units: cm/s (centimeters per second)] Mean (Standard Error)		
9:00 am	**-0.0 (0.454)**	**-0.8 (0.448)**
1:00 pm	**-0.6 (0.459)**	**-1.2 (0.460)**
5:00 pm	**0.5 (0.459)**	**0.2 (0.466)**
9:00 pm	**0.4 (0.454)**	**-0.8 (0.448)**
12:00 am	**-0.8 (0.466)**	**-1.4 (0.454)**
3:00 am	**-0.1 (0.454)**	**-0.6 (0.459)**
6:00 am	**-0.2 (0.466)**	**-0.5 (0.448)**

No statistical analysis provided for Mean Change From Baseline in End Diastolic Velocity in the Ophthalmic Artery at Week 6

11. Secondary: Mean Change From Baseline in Peak Systolic Velocity in the Ophthalmic Artery at Week 6 [Time Frame: Week 0, Week 6 (period-based)]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in Peak Systolic Velocity in the Ophthalmic Artery at Week 6
Measure Description	Peak systolic velocity in the ophthalmic artery was assessed using Color Doppler Imaging (CDI). Assessments were made at 7 time points over a 24-hour period.
Time Frame	Week 0, Week 6 (period-based)
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 patients who received study medication and completed the on-therapy follow-up study visit in both periods (ITT). The analysis is based on patient eye-matched image data received.

Reporting Groups

	Description
AZARGA	One drop in the study eye, twice daily (9:00 and 21:00), for six weeks
COMBIGAN	One drop in the study eye, twice daily (9:00 and 21:00), for six weeks

Measured Values

	AZARGA	COMBIGAN
Number of Participants Analyzed [units: participants]	**32**	**32**
Number of eyes Analyzed		

[units: eyes]	**41**	**41**
Mean Change From Baseline in Peak Systolic Velocity in the Ophthalmic Artery at Week 6 [units: cm/s (centimeters per second)] Median (Standard Error)		
9:00 am	**-1.0 (1.237)**	**-3.8 (1.221)**
1:00 pm	**-0.7 (1.251)**	**-1.4 (1.254)**
5:00 pm	**2.2 (1.251)**	**1.3 (1.267)**
9:00 pm	**2.2 (1.237)**	**-1.4 (1.221)**
12:00 am	**-2.3 (1.268)**	**-3.1 (1.235)**
3:00 am	**0.2 (1.235)**	**0.0 (1.250)**
6:00 am	**-0.6 (1.267)**	**1.5 (1.221)**

No statistical analysis provided for Mean Change From Baseline in Peak Systolic Velocity in the Ophthalmic Artery at Week 6

12. Secondary: Mean Change From Baseline in Peak Systolic Velocity in the Central Retinal Artery at Week 6 [Time Frame: Week 0, Week 6 (period-based)]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in Peak Systolic Velocity in the Central Retinal Artery at Week 6
Measure Description	Peak systolic velocity in the central retinal artery was assessed using Color Doppler Imaging (CDI). Assessments were made at 7 time points over a 24-hour period.
Time Frame	Week 0, Week 6 (period-based)
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 patients who received study medication and completed the on-therapy follow-up study visit in both periods (ITT). The analysis is based on patient eye-matched image data received.

Reporting Groups

	Description
AZARGA	One drop in the study eye, twice daily (9:00 and 21:00), for six weeks
COMBIGAN	One drop in the study eye, twice daily (9:00 and 21:00), for six weeks

Measured Values

	AZARGA	COMBIGAN
Number of Participants Analyzed [units: participants]	**32**	**32**
Number of eyes Analyzed [units: eyes]	**41**	**41**
Mean Change From Baseline in Peak Systolic Velocity in the Central Retinal Artery at Week 6 [units: cm/s (centimeters per second)] Mean (Standard Error)		
9:00 am	**0.9 (0.571)**	**0.7 (0.565)**
1:00 pm	**-0.2 (0.577)**	**0.3 (0.578)**

5:00 pm	**1.0 (0.577)**	**0.6 (0.565)**
9:00 pm	**0.9 (0.565)**	**-0.5 (0.565)**
12:00 am	**1.9 (0.577)**	**-0.5 (0.565)**
3:00 am	**0.2 (0.565)**	**-1.1 (0.570)**
6:00 am	**0.2 (0.571)**	**0.9 (0.565)**

No statistical analysis provided for Mean Change From Baseline in Peak Systolic Velocity in the Central Retinal Artery at Week 6

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Adverse events were collected for the duration of the study.
Additional Description	The safety population is defined as patients who received study medication.

Reporting Groups

	Description
AZARGA	One drop in the study eye, twice daily (9:00 and 21:00), for six weeks
COMBIGAN	One drop in the study eye, twice daily (9:00 and 21:00), for six weeks

Serious Adverse Events

	AZARGA	COMBIGAN
Total, serious adverse events		
# participants affected / at risk	**1/34 (2.94%)**	**0/34 (0.00%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Breast Cancer [1]		
# participants affected / at risk	**1/34 (2.94%)**	**0/34 (0.00%)**

[1] Recurrent Illness

Other Adverse Events

Hide Other Adverse Events

Time Frame	Adverse events were collected for the duration of the study.
Additional Description	The safety population is defined as patients who received study medication.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
AZARGA	One drop in the study eye, twice daily (9:00 and 21:00), for six weeks
COMBIGAN	One drop in the study eye, twice daily (9:00 and 21:00), for six weeks

Other Adverse Events

	AZARGA	COMBIGAN

Total, other (not including serious) adverse events		
# participants affected / at risk	**0/34 (0.00%)**	**0/34 (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:

Name/Title: Director, Global Medical Affairs
Organization: Alcon Research, Ltd.
phone: 1-888-451-3937

No publications provided

Responsible Party:	Alcon Research
ClinicalTrials.gov Identifier:	NCT00800540 History of Changes
Other Study ID Numbers:	C-07-16 2007-005936-99 (EudraCT Number)
Study First Received:	December 1, 2008
Results First Received:	January 31, 2013
Last Updated:	March 20, 2013
Health Authority:	Greece: Ethics Committee