Trial record **1 of 1** for: MAF-AGN-OPH-GLA-010

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Safety and Efficacy of Bimatoprost/Timolol Fixed Combination Versus Latanoprost in Patients With Open-Angle Glaucoma Who Have Never Been Treated

ClinicalTrials.gov Identifier: NCT01243567

Recruitment Status : Completed
First Posted : November 18, 2010
Results First Posted : February 26, 2013
Last Update Posted : February 26, 2013

Sponsor:
Allergan

Information provided by (Responsible Party):
Allergan

Study Details | Tabular View | Study Results | Disclaimer

How to Read a Study Record

Study Type:	Interventional
Study Design:	Allocation: Randomized; Intervention Model: Parallel Assignment; Masking: Single (Investigator); Primary Purpose: Treatment
Condition:	Glaucoma, Open-Angle
Interventions:	Drug: bimatoprost 0.03%/timolol 0.5% combination ophthalmic solution Drug: latanoprost 0.005% 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
No text entered.

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
Bimatoprost 0.03%/Timolol 0.5% Combination Ophthalmic Solution	Bimatoprost 0.03%/timolol 0.5% combination ophthalmic solution (GANfort®) administered to each eye requiring treatment, once daily in the

	evening for 3 months.
Latanoprost 0.005% Ophthalmic Solution	Latanoprost 0.005% ophthalmic solution (Xalatan®) administered to each eye requiring treatment, once daily in the evening for 3 months.

Participant Flow: Overall Study

	Bimatoprost 0.03%/Timolol 0.5% Combination Ophthalmic Solution	Latanoprost 0.005% Ophthalmic Solution
STARTED	**43**	**38**
COMPLETED	**42**	**38**
NOT COMPLETED	**1**	**0**

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

Bimatoprost 0.03%/Timolol 0.5% Combination Ophthalmic Solution	Bimatoprost 0.03%/timolol 0.5% combination ophthalmic solution (GANfort®) administered to each eye requiring treatment, once daily in the evening for 3 months.
Latanoprost 0.005% Ophthalmic Solution	Latanoprost 0.005% ophthalmic solution (Xalatan®) administered to each eye requiring treatment, once daily in the evening for 3 months.
Total	Total of all reporting groups

Baseline Measures

	Bimatoprost 0.03%/Timolol 0.5% Combination Ophthalmic Solution	**Latanoprost 0.005% Ophthalmic Solution**	**Total**
Overall Participants Analyzed [Units: Participants]	**43**	**38**	**81**
Age [Units: Years]	**65.9 (10.24)**	**63.1 (13.72)**	**64.6 (12.01)**

Mean (Standard Deviation)			
Gender [Units: Participants]			
Female	**20**	**18**	**38**
Male	**23**	**20**	**43**

Outcome Measures

Hide All Outcome Measures

1. **Primary: Change From Baseline in Average Intraocular Pressure (IOP) [Time Frame: Baseline, Month 3]**

Measure Type	Primary
Measure Title	Change From Baseline in Average Intraocular Pressure (IOP)
Measure Description	IOP is a measurement of the fluid pressure inside the eye. For each patient, the IOP is the average of the two eyes. The average IOP is the average of the 08:00, 12:00 and 16:00 hour time points at each visit for each patient. A negative number change from Baseline indicates a reduction in average IOP (improvement).
Time Frame	Baseline, Month 3

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.
Intent to Treat: all randomized patients.

Reporting Groups

	Description
Bimatoprost 0.03%/Timolol 0.5% Combination Ophthalmic Solution	Bimatoprost 0.03%/timolol 0.5%

	combination ophthalmic solution (GANfort®) administered to each eye requiring treatment, once daily in the evening for 3 months.
Latanoprost 0.005% Ophthalmic Solution	Latanoprost 0.005% ophthalmic solution (Xalatan®) administered to each eye requiring treatment, once daily in the evening for 3 months.

Measured Values

	Bimatoprost 0.03%/Timolol 0.5% Combination Ophthalmic Solution	**Latanoprost 0.005% Ophthalmic Solution**
Participants Analyzed [Units: Participants]	**43**	**38**
Change From Baseline in Average Intraocular Pressure (IOP) [Units: Millimeters of Mercury (mmHg)] Mean (Standard Deviation)		
Baseline	**28.4 (3.35)**	**28.5 (2.57)**
Change from Baseline at Month 3	**-13.5 (4.48)**	**-11.4 (3.19)**

No statistical analysis provided for Change From Baseline in Average Intraocular Pressure (IOP)

2. Secondary: Change From Baseline IOP [Time Frame: Baseline, Month 3]

Measure Type	Secondary
Measure Title	Change From Baseline IOP
Measure Description	

	IOP is a measurement of the fluid pressure inside the eye. For each patient, the IOP is the average of the two eyes. IOP is recorded at the 08:00 (8:00 am), 12:00 (noon) and 16:00 (4:00 pm) hour time points for each patient at each visit. A negative number change from Baseline indicates a reduction in IOP (improvement).
Time Frame	Baseline, Month 3

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.
Intent to Treat: all randomized patients.

Reporting Groups

	Description
Bimatoprost 0.03%/Timolol 0.5% Combination Ophthalmic Solution	Bimatoprost 0.03%/timolol 0.5% combination ophthalmic solution (GANfort®) administered to each eye requiring treatment, once daily in the evening for 3 months.
Latanoprost 0.005% Ophthalmic Solution	Latanoprost 0.005% ophthalmic solution (Xalatan®) administered to each eye requiring treatment, once daily in the evening for 3 months.

Measured Values

	Bimatoprost 0.03%/Timolol 0.5% Combination Ophthalmic Solution	**Latanoprost 0.005% Ophthalmic Solution**
	43	**38**

Participants Analyzed [Units: Participants]		
Change From Baseline IOP [Units: Millimeters of Mercury (mmHg)] Mean (Standard Deviation)		
Baseline-08:00	**29.7 (2.97)**	**29.6 (2.93)**
Baseline-12:00	**28.7 (4.46)**	**29.0 (2.60)**
Baseline-16:00	**26.8 (4.01)**	**26.8 (3.73)**
Change from Baseline at Month 3-08:00	**-14.6 (4.04)**	**-12.3 (3.64)**
Change from Baseline at Month 3-12:00	**-13.6 (5.50)**	**-11.8 (3.14)**
Change from Baseline at Month 3-16:00	**-12.4 (5.16)**	**-10.3 (4.24)**

No statistical analysis provided for Change From Baseline IOP

3. Secondary: Percentage of Patients Reaching a Predefined Target Pressure Threshold [Time Frame: Baseline, Month 3]

Measure Type	Secondary
Measure Title	Percentage of Patients Reaching a Predefined Target Pressure Threshold
Measure Description	IOP is a measurement of the fluid pressure inside the eye. For each patient, the IOP is the average of the two eyes. The predefined target pressure thresholds are at least a 20%, 30%, 40%, and 50% reduction in IOP from baseline.
Time Frame	Baseline, Month 3

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.

Intent to Treat: all randomized patients.

Reporting Groups

	Description
Bimatoprost 0.03%/Timolol 0.5% Combination Ophthalmic Solution	Bimatoprost 0.03%/timolol 0.5% combination ophthalmic solution (GANfort®) administered to each eye requiring treatment, once daily in the evening for 3 months.
Latanoprost 0.005% Ophthalmic Solution	Latanoprost 0.005% ophthalmic solution (Xalatan®) administered to each eye requiring treatment, once daily in the evening for 3 months.

Measured Values

	Bimatoprost 0.03%/Timolol 0.5% Combination Ophthalmic Solution	Latanoprost 0.005% Ophthalmic Solution
Participants Analyzed [Units: Participants]	**43**	**38**
Percentage of Patients Reaching a Predefined Target Pressure Threshold [Units: Percentage of Patients]		
Decrease of at Least 20%	**97.7**	**100.0**
Decrease of at Least 30%	**90.7**	**86.8**
Decrease of at Least 40%	**74.4**	**47.4**
Decrease of at Least 50%	**46.5**	**15.8**

No statistical analysis provided for Percentage of Patients Reaching a Predefined Target Pressure Threshold

4. **Secondary: Absolute Difference Between Patient's Highest IOP Reading at Baseline (Day 0) and the Corresponding IOP Reading [Time Frame: Baseline, Month 3]**

Measure Type	Secondary
Measure Title	Absolute Difference Between Patient's Highest IOP Reading at Baseline (Day 0) and the Corresponding IOP Reading
Measure Description	IOP is a measurement of the fluid pressure inside the eye. Two or three measurements of IOP are taken for each eye at each time point. The highest IOP values between the two eyes for each patient at each time point are used to calculate the absolute difference.
Time Frame	Baseline, Month 3

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.
Intent to Treat: all randomized patients.

Reporting Groups

	Description
Bimatoprost 0.03%/Timolol 0.5% Combination Ophthalmic Solution	Bimatoprost 0.03%/timolol 0.5% combination ophthalmic solution (GANfort®) administered to each eye requiring treatment, once daily in the evening for 3 months.
Latanoprost 0.005% Ophthalmic Solution	Latanoprost 0.005% ophthalmic solution (Xalatan®) administered

	to each eye requiring treatment, once daily in the evening for 3 months.

Measured Values

	Bimatoprost 0.03%/Timolol 0.5% Combination Ophthalmic Solution	Latanoprost 0.005% Ophthalmic Solution
Participants Analyzed [Units: Participants]	**43**	**38**
Absolute Difference Between Patient's Highest IOP Reading at Baseline (Day 0) and the Corresponding IOP Reading [Units: Millimeters of Mercury (mmHg)] Mean (Standard Deviation)		
Baseline	**30.4 (3.19)**	**30.3 (2.54)**
Absolute Difference at Month 3	**-15.3 (4.44)**	**-12.9 (3.82)**

No statistical analysis provided for Absolute Difference Between Patient's Highest IOP Reading at Baseline (Day 0) and the Corresponding IOP Reading

5. Secondary: Absolute Difference Between Patient's Lowest IOP Reading at Baseline (Day 0) and the Corresponding IOP Reading [Time Frame: Baseline, Month 3]

Measure Type	Secondary
Measure Title	Absolute Difference Between Patient's Lowest IOP Reading at Baseline (Day 0) and the Corresponding IOP Reading
Measure Description	IOP is a measurement of the fluid pressure inside the eye. Two or three measurements of IOP are taken for each eye at each time point. The lowest IOP values between the two eyes for each patient at each time point are used to calculate the absolute difference.

Time Frame	Baseline, Month 3

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.
Intent to Treat: all randomized patients.

Reporting Groups

	Description
Bimatoprost 0.03%/Timolol 0.5% Combination Ophthalmic Solution	Bimatoprost 0.03%/timolol 0.5% combination ophthalmic solution (GANfort®) administered to each eye requiring treatment, once daily in the evening for 3 months.
Latanoprost 0.005% Ophthalmic Solution	Latanoprost 0.005% ophthalmic solution (Xalatan®) administered to each eye requiring treatment, once daily in the evening for 3 months.

Measured Values

	Bimatoprost 0.03%/Timolol 0.5% Combination Ophthalmic Solution	**Latanoprost 0.005% Ophthalmic Solution**
Participants Analyzed [Units: Participants]	**43**	**38**
Absolute Difference Between Patient's Lowest IOP Reading at Baseline (Day 0) and the Corresponding IOP Reading		

[Units: Millimeters of Mercury (mmHg)] Mean (Standard Deviation)		
Baseline	**26.2 (4.04)**	**26.5 (3.44)**
Absolute Difference at Month 3	**-11.8 (5.23)**	**-9.9 (3.71)**

No statistical analysis provided for Absolute Difference Between Patient's Lowest IOP Reading at Baseline (Day 0) and the Corresponding IOP Reading

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Reporting Groups

	Description
Bimatoprost 0.03%/Timolol 0.5% Combination Ophthalmic Solution	Bimatoprost 0.03%/timolol 0.5% combination ophthalmic solution (GANfort®) administered to each eye requiring treatment, once daily in the evening for 3 months.
Latanoprost 0.005% Ophthalmic Solution	Latanoprost 0.005% ophthalmic solution (Xalatan®)

	administered to each eye requiring treatment, once daily in the evening for 3 months.

Serious Adverse Events

	Bimatoprost 0.03%/Timolol 0.5% Combination Ophthalmic Solution	Latanoprost 0.005% Ophthalmic Solution
Total, Serious Adverse Events		
# participants affected / at risk	**1/43 (2.33%)**	**0/38 (0.00%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Colon Cancer † 1		
# participants affected / at risk	**1/43 (2.33%)**	**0/38 (0.00%)**

† Events were collected by systematic assessment

1 Term from vocabulary, MedDRA version 12.1

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Bimatoprost 0.03%/Timolol 0.5% Combination Ophthalmic Solution	Bimatoprost 0.03%/timolol 0.5% combination ophthalmic solution (GANfort®) administered to each eye requiring treatment, once daily in the evening for 3 months.
Latanoprost 0.005% Ophthalmic Solution	Latanoprost 0.005% ophthalmic solution (Xalatan®) administered to each eye requiring treatment, once daily in the evening for 3 months.

Other Adverse Events

	Bimatoprost 0.03%/Timolol 0.5% Combination Ophthalmic Solution	Latanoprost 0.005% Ophthalmic Solution
Total, Other (not including serious) Adverse Events		
# participants affected / at risk	**9/43 (20.93%)**	**10/38 (26.32%)**
Eye disorders		

Ocular Hyperaemia * 1		
# participants affected / at risk	**7/43 (16.28%)**	**4/38 (10.53%)**
Blepharitis * 1		
# participants affected / at risk	**1/43 (2.33%)**	**2/38 (5.26%)**
Conjunctival Hyperaemia † 1		
# participants affected / at risk	**1/43 (2.33%)**	**2/38 (5.26%)**
Foreign Body Sensation in Eyes * 1		
# participants affected / at risk	**0/43 (0.00%)**	**2/38 (5.26%)**

† Events were collected by systematic assessment

* Events were collected by non-systematic assessment

1 Term from vocabulary, MedDRA version 12.1

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
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:** A 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 90 days from the time submitted to the sponsor for review. The sponsor cannot require changes to the communication and cannot extend the embargo.

Results Point of Contact:

Name/Title: Vice President Medical Affairs,
Organization: Allergan, Inc
phone: 714-246-4500
e-mail: clinicaltrials@allergan.com

Responsible Party:	Allergan
ClinicalTrials.gov Identifier:	NCT01243567 History of Changes
Other Study ID Numbers:	**MAF-AGN-OPH-GLA-010**
	2009-012799-28 (EudraCT Number)
First Submitted:	November 17, 2010
First Posted:	November 18, 2010
Results First Submitted:	January 22, 2013
Results First Posted:	February 26, 2013

Last Update Posted: February 26, 2013