ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: 03/22/2013

ClinicalTrials.gov ID: NCT01177098

Study Identification

Unique Protocol ID:	192024-050
Brief Title:	Safety and Efficacy of a New Formulation of Bimatoprost/Timolol Ophthalmic Solution Compared With Bimatoprost/Timolol Ophthalmic Solution in Patients With Glaucoma or Ocular Hypertension
Official Title:	
Secondary IDs:	2010-021507-24 [EudraCT Number]

Study Status

Record Verification:	March 2013
Overall Status:	Completed
Study Start:	October 2010
Primary Completion:	February 2012 [Actual]
Study Completion:	February 2012 [Actual]

Sponsor/Collaborators

Sponsor:	Allergan
Responsible Party:	Sponsor
Collaborators:	

Oversight

FDA Regulated?:	Yes
Applicable Trial?:	Section 801 Clinical Trial? Yes

	Delayed Posting? No
IND/IDE Protocol?:	Yes
IND/IDE Information:	Grantor: CDER IND/IDE Number: 62,774 Serial Number: Has Expanded Access? No
Review Board:	Approval Status: Board Name: Board Affiliation: Phone: Email:
Data Monitoring?:	No
Plan to Share Data?:	
Oversight Authorities:	United States: Food and Drug Administration

Study Description

Brief Summary:	This study will evaluate the safety and efficacy of bimatoprost/timolol formulation A ophthalmic solution with Ganfort® (bimatoprost 0.03%/timolol 0.5% ophthalmic solution) once daily for 12 weeks in patients with glaucoma or ocular hypertension.
Detailed Description:	

Conditions

Conditions:	Glaucoma Ocular Hypertension
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 3
Intervention Model:	Parallel Assignment
Number of Arms:	2
Masking:	Double Blind (Subject, Investigator)

Allocation:	Randomized
Endpoint Classification:	Safety/Efficacy Study
Enrollment:	561 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: bimatoprost/timolol formulation A One drop of bimatoprost/timolol formulation A fixed combination ophthalmic solution administered in each eye every morning for 12 weeks.	Drug: bimatoprost /timolol formulation A fixed combination ophthalmic solution One drop of bimatoprost/timolol formulation A fixed combination ophthalmic solution administered in each eye every morning for 12 weeks.
Active Comparator: bimatoprost/timolol fixed combination ophthalmic solution One drop of bimatoprost 0.03%/timolol 0.5% fixed combination ophthalmic solution (Ganfort®) administered in each eye every morning for 12 weeks.	Drug: bimatoprost/timolol fixed combination ophthalmic solution One drop of bimatoprost 0.03%/timolol 0.5% fixed combination ophthalmic solution (Ganfort®) administered in each eye every morning for 12 weeks. Other Names: • GANFORT®

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age:	18 Years
Maximum Age:	
Gender:	Both
Accepts Healthy Volunteers?:	No
Criteria:	Inclusion Criteria:

- Patient has ocular hypertension or glaucoma in both eyes
- Requires IOP-lowering therapy in each eye

Exclusion Criteria:

- Active or recurrent eye disease that would interfere with interpretation of study data in either eye
- History of any eye surgery or laser in either eye within 6 months
- Required chronic use of other eye medications during the study
- Anticipated wearing of contact lenses during the study.
- Intermittent use of oral, intramuscular, or intravenous corticosteroids within 21 days

Contacts/Locations

Study Officials: Medical Director
Study Director
Allergan, Inc.

Locations: Israel
Tel Aviv, Israel

Australia, New South Wales
Sydney, New South Wales, Australia

Germany
Leipzig, Germany

Czech Republic
Brno, Czech Republic

Hungary
Budapest, Hungary

Spain
Valencia, Spain

Russian Federation
Saint-Petersburg, Russian Federation

United Kingdom
London, England, United Kingdom

United States, California
Artesia, California, United States

References

Citations:

Links:

Study Data/Documents:

Study Results

Participant Flow

Reporting Groups

	Description
Bimatoprost/Timolol Formulation A	One drop of bimatoprost/timolol formulation A fixed combination ophthalmic solution administered in each eye every morning for 12 weeks.
Bimatoprost/Timolol Fixed Combination Ophthalmic Solution	One drop of bimatoprost 0.03%/timolol 0.5% fixed combination ophthalmic solution (Ganfort®) administered in each eye every morning for 12 weeks.

Overall Study

	Bimatoprost/Timolol Formulation A	Bimatoprost/Timolol Fixed Combination Ophthalmic Solution
Started	278	283
Completed	269	271
Not Completed	9	12

Baseline Characteristics

Reporting Groups

	Description
Bimatoprost/Timolol Formulation A	One drop of bimatoprost/timolol formulation A fixed combination ophthalmic solution administered in each eye every morning for 12 weeks.
Bimatoprost/Timolol Fixed Combination Ophthalmic Solution	One drop of bimatoprost 0.03%/timolol 0.5% fixed combination ophthalmic solution (Ganfort®) administered in each eye every morning for 12 weeks.

Baseline Measures

	Bimatoprost/Timolol Formulation A	Bimatoprost/Timolol Fixed Combination Ophthalmic Solution	Total
Number of Participants	278	283	561
Age, Customized [units: Participants]			
<45 Years	12	13	25
45 to 65 Years	132	135	267

	Bimatoprost/Timolol Formulation A	Bimatoprost/Timolol Fixed Combination Ophthalmic Solution	Total
>65 Years	134	135	269
Gender, Male/Female [units: Participants]			
Female	159	162	321
Male	119	121	240

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Change From Baseline in Worse Eye Intraocular Pressure (IOP) at Each Hour Evaluated at Week 12
Measure Description	Intraocular pressure (IOP) is a measurement of the fluid pressure inside the eye. IOP was evaluated at Baseline and Week 12 at Hour 0, Hour 2 and Hour 8 in the worse eye, defined as the eye with the worse (higher) IOP at baseline. A negative number change from baseline indicates a reduction in IOP (improvement).
Time Frame	Baseline, Week 12
Safety Issue?	No

Analysis Population Description

Per-protocol population included randomized participants who did not have a protocol violation that significantly affected the conduct or the results of the trial.

Reporting Groups

	Description
Bimatoprost/Timolol Formulation A	One drop of bimatoprost/timolol formulation A fixed combination ophthalmic solution administered in each eye every morning for 12 weeks.
Bimatoprost/Timolol Fixed Combination Ophthalmic Solution	One drop of bimatoprost 0.03%/timolol 0.5% fixed combination ophthalmic solution (Ganfort®) administered in each eye every morning for 12 weeks.

Measured Values

	Bimatoprost/Timolol Formulation A	Bimatoprost/Timolol Fixed Combination Ophthalmic Solution
Number of Participants Analyzed	256	260
Change From Baseline in Worse Eye Intraocular Pressure (IOP) at Each Hour Evaluated at Week 12 [units: mm Hg] Mean (Standard Deviation)		

	Bimatoprost/Timolol Formulation A	Bimatoprost/Timolol Fixed Combination Ophthalmic Solution
Baseline_Hour 0	25.41 (2.232)	25.38 (2.209)
Baseline_Hour 2 (n=255,260)	24.79 (2.676)	24.72 (2.470)
Baseline_Hour 8 (n=254,259)	23.88 (3.008)	23.82 (2.747)
Change from baseline at Week 12_Hour 0 (n=244,237)	-9.06 (3.216)	-8.72 (3.088)
Change from baseline at Week 12_Hour 2 (n=235,235)	-8.53 (3.520)	-8.38 (3.297)
Change from baseline at Week 12_Hour 8 (n=237,234)	-7.98 (3.435)	-7.72 (3.172)

2. Primary Outcome Measure:

Measure Title	Average Eye Intraocular Pressure (IOP) at Each Hour Evaluated at Week 2
Measure Description	Intraocular pressure (IOP) is a measurement of the fluid pressure inside the eye. Average eye IOP is the average IOP of both eyes and was evaluated at Week 2 at Hour 0, Hour 2 and Hour 8.
Time Frame	Week 2
Safety Issue?	No

Analysis Population Description

Intent-to-treat population included all randomized participants.

Reporting Groups

	Description
Bimatoprost/Timolol Formulation A	One drop of bimatoprost/timolol formulation A fixed combination ophthalmic solution administered in each eye every morning for 12 weeks.
Bimatoprost/Timolol Fixed Combination Ophthalmic Solution	One drop of bimatoprost 0.03%/timolol 0.5% fixed combination ophthalmic solution (Ganfort®) administered in each eye every morning for 12 weeks.

Measured Values

	Bimatoprost/Timolol Formulation A	Bimatoprost/Timolol Fixed Combination Ophthalmic Solution
Number of Participants Analyzed	278	283

	Bimatoprost/Timolol Formulation A	Bimatoprost/Timolol Fixed Combination Ophthalmic Solution
Average Eye Intraocular Pressure (IOP) at Each Hour Evaluated at Week 2 [units: mm Hg] Mean (Standard Deviation)		
Week 2_Hour 0	16.23 (2.746)	16.49 (2.887)
Week 2_Hour 2	16.05 (2.877)	16.23 (2.826)
Week 2_Hour 8	15.49 (2.596)	15.83 (2.987)

3. Primary Outcome Measure:

Measure Title	Average Eye Intraocular Pressure (IOP) at Each Hour Evaluated at Week 6
Measure Description	Intraocular pressure (IOP) is a measurement of the fluid pressure inside the eye. Average eye IOP is the average IOP of both eyes and was evaluated at Week 6 at Hour 0, Hour 2 and Hour 8.
Time Frame	Week 6
Safety Issue?	No

Analysis Population Description

Intent-to-treat population included all randomized participants.

Reporting Groups

	Description
Bimatoprost/Timolol Formulation A	One drop of bimatoprost/timolol formulation A fixed combination ophthalmic solution administered in each eye every morning for 12 weeks.
Bimatoprost/Timolol Fixed Combination Ophthalmic Solution	One drop of bimatoprost 0.03%/timolol 0.5% fixed combination ophthalmic solution (Ganfort®) administered in each eye every morning for 12 weeks.

Measured Values

	Bimatoprost/Timolol Formulation A	Bimatoprost/Timolol Fixed Combination Ophthalmic Solution
Number of Participants Analyzed	278	283
Average Eye Intraocular Pressure (IOP) at Each Hour Evaluated at Week 6 [units: mm Hg]		

	Bimatoprost/Timolol Formulation A	Bimatoprost/Timolol Fixed Combination Ophthalmic Solution
Mean (Standard Deviation)		
Week 6_Hour 0	16.28 (2.754)	16.31 (2.874)
Week 6_Hour 2	15.90 (2.910)	16.17 (2.894)
Week 6_Hour 8	15.71 (2.755)	15.82 (2.926)

4. Primary Outcome Measure:

Measure Title	Average Eye Intraocular Pressure (IOP) at Each Hour Evaluated at Week 12
Measure Description	Intraocular pressure (IOP) is a measurement of the fluid pressure inside the eye. Average eye IOP is the average IOP of both eyes and was evaluated at Week 12 at Hour 0, Hour 2 and Hour 8.
Time Frame	Week 12
Safety Issue?	No

Analysis Population Description

Intent-to-treat population included all randomized participants.

Reporting Groups

	Description
Bimatoprost/Timolol Formulation A	One drop of bimatoprost/timolol formulation A fixed combination ophthalmic solution administered in each eye every morning for 12 weeks.
Bimatoprost/Timolol Fixed Combination Ophthalmic Solution	One drop of bimatoprost 0.03%/timolol 0.5% fixed combination ophthalmic solution (Ganfort®) administered in each eye every morning for 12 weeks.

Measured Values

	Bimatoprost/Timolol Formulation A	Bimatoprost/Timolol Fixed Combination Ophthalmic Solution
Number of Participants Analyzed	278	283
Average Eye Intraocular Pressure (IOP) at Each Hour Evaluated at Week 12 [units: mm Hg] Mean (Standard Deviation)		
Week 12_Hour 0	16.29 (2.783)	16.56 (2.643)

	Bimatoprost/Timolol Formulation A	Bimatoprost/Timolol Fixed Combination Ophthalmic Solution
Week 12_Hour 2	16.18 (2.845)	16.37 (2.699)
Week 12_Hour 8	15.85 (2.786)	16.09 (2.714)

5. Secondary Outcome Measure:

Measure Title	Change From Baseline in Worse Eye IOP at Each Hour Evaluated at Week 12
Measure Description	Intraocular pressure (IOP) is a measurement of the fluid pressure inside the eye. IOP was evaluated at Baseline and Week 12 at Hour 0, Hour 2 and Hour 8 in the worse eye, defined as the eye with the worse (higher) IOP at baseline. A negative number change from baseline indicates a reduction in IOP (improvement).
Time Frame	Baseline, Week 12
Safety Issue?	No

Analysis Population Description

Intent-to-treat population included all randomized participants.

Reporting Groups

	Description
Bimatoprost/Timolol Formulation A	One drop of bimatoprost/timolol formulation A fixed combination ophthalmic solution administered in each eye every morning for 12 weeks.
Bimatoprost/Timolol Fixed Combination Ophthalmic Solution	One drop of bimatoprost 0.03%/timolol 0.5% fixed combination ophthalmic solution (Ganfort®) administered in each eye every morning for 12 weeks.

Measured Values

	Bimatoprost/Timolol Formulation A	Bimatoprost/Timolol Fixed Combination Ophthalmic Solution
Number of Participants Analyzed	278	283
Change From Baseline in Worse Eye IOP at Each Hour Evaluated at Week 12 [units: mm Hg] Mean (Standard Deviation)		
Baseline_Hour 0	25.34 (2.233)	25.30 (2.244)
Baseline_Hour 2	24.71 (2.700)	24.61 (2.536)

	Bimatoprost/Timolol Formulation A	Bimatoprost/Timolol Fixed Combination Ophthalmic Solution
Baseline_Hour 8	23.81 (2.989)	23.80 (2.795)
Change from baseline at Week 12_Hour 0	-8.94 (3.290)	-8.51 (3.253)
Change from baseline at Week 12_Hour 2	-8.44 (3.646)	-8.08 (3.504)
Change from baseline at Week 12_Hour 8	-7.87 (3.496)	-7.52 (3.362)

6. Secondary Outcome Measure:

Measure Title	Change From Baseline in Average Eye IOP at Each Hour Evaluated at Week 12
Measure Description	Intraocular pressure (IOP) is a measurement of the fluid pressure inside the eye. Average eye IOP was evaluated at Baseline and Week 12 at Hour 0, Hour 2 and Hour 8. Average eye IOP is defined as the average of the IOP in both eyes. A negative number change from baseline indicates a reduction in IOP (improvement).
Time Frame	Baseline, Week 12
Safety Issue?	No

Analysis Population Description

Intent-to-treat population included all randomized participants.

Reporting Groups

	Description
Bimatoprost/Timolol Formulation A	One drop of bimatoprost/timolol formulation A fixed combination ophthalmic solution administered in each eye every morning for 12 weeks.
Bimatoprost/Timolol Fixed Combination Ophthalmic Solution	One drop of bimatoprost 0.03%/timolol 0.5% fixed combination ophthalmic solution (Ganfort®) administered in each eye every morning for 12 weeks.

Measured Values

	Bimatoprost/Timolol Formulation A	Bimatoprost/Timolol Fixed Combination Ophthalmic Solution
Number of Participants Analyzed	278	283
Change From Baseline in Average Eye IOP at Each Hour Evaluated at Week 12 [units: mm Hg] Mean (Standard Deviation)		

	Bimatoprost/Timolol Formulation A	Bimatoprost/Timolol Fixed Combination Ophthalmic Solution
Baseline_Hour 0	24.94 (2.116)	24.86 (2.131)
Baseline_Hour 2	24.29 (2.515)	24.23 (2.426)
Baseline_Hour 8	23.42 (2.904)	23.36 (2.703)
Change from baseline at Week 12_Hour 0	-8.65 (3.109)	-8.30 (3.009)
Change from baseline at Week 12_Hour 2	-8.11 (3.392)	-7.86 (3.413)
Change from baseline at Week 12_Hour 8	-7.57 (3.395)	-7.27 (3.226)

Reported Adverse Events

Time Frame	[Not specified]
Additional Description	The safety population (all treated participants) was used to calculate the number of participants at risk for Serious Adverse Events and Adverse Events.

Reporting Groups

	Description
Bimatoprost/Timolol Formulation A	One drop of bimatoprost/timolol formulation A fixed combination ophthalmic solution administered in each eye every morning for 12 weeks.
Bimatoprost/Timolol Fixed Combination Ophthalmic Solution	One drop of bimatoprost 0.03%/timolol 0.5% fixed combination ophthalmic solution (Ganfort®) administered in each eye every morning for 12 weeks.

Serious Adverse Events

	Bimatoprost/Timolol Formulation A	Bimatoprost/Timolol Fixed Combination Ophthalmic Solution
	Affected/At Risk (%)	Affected/At Risk (%)
Total	4/278 (1.44%)	4/282 (1.42%)
General disorders		
Non-cardiac chest pain [A] †	0/278 (0%)	1/282 (0.35%)
Musculoskeletal and connective tissue disorders		

	Bimatoprost/Timolol Formulation A	Bimatoprost/Timolol Fixed Combination Ophthalmic Solution
	Affected/At Risk (%)	Affected/At Risk (%)
Lumbar spinal stenosis [A] †	1/278 (0.36%)	0/282 (0%)
Osteoarthritis [A] †	1/278 (0.36%)	0/282 (0%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Lung neoplasm malignant [A] †	0/278 (0%)	1/282 (0.35%)
Non-Hodgkin's lymphoma [A] †	0/278 (0%)	1/282 (0.35%)
Prostate cancer [A] †	1/278 (0.36%)	0/282 (0%)
Nervous system disorders		
Cerebellar infarction [A] †	0/278 (0%)	1/282 (0.35%)
Vascular disorders		
Intermittent claudication [A] *	1/278 (0.36%)	0/282 (0%)

† Indicates events were collected by systematic assessment.
* Indicates events were collected by non-systematic methods.
A Term from vocabulary, MedDRA 14.1

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	Bimatoprost/Timolol Formulation A	Bimatoprost/Timolol Fixed Combination Ophthalmic Solution
	Affected/At Risk (%)	Affected/At Risk (%)
Total	59/278 (21.22%)	55/282 (19.5%)
Eye disorders		
Conjunctival hyperaemia [A] †	59/278 (21.22%)	55/282 (19.5%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA 14.1

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

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/Official Title: Therapeutic Area Head,
Organization: Allergan, Inc
Phone: 714-246-4500
Email: clinicaltrials@allergan.com