Sponsor

Alcon Research, Ltd.

Generic Drug Name

Travoprost/timolol maleate fixed combination

Trial Indications

Ocular Hypertension and Primary Open-Angle Glaucoma

Protocol Number

RDG-10-243

Protocol Title

Assessing the Safety and Efficacy of Changing to DuoTrav® (Travoprost 0.004%/Timolol 0.5% Fixed Combination), as Replacement Therapy in Patients Uncontrolled on Bimatoprost 0.03%/Timolol 0.5% Therapy (Fixed or Unfixed) Combination

Clinical Trial Phase

IV

Study Start/End Dates

21 October 2010 to 17 February 2011

Reason for Termination (if applicable)

Not applicable

Study Design/Methodology

This was a prospective, multicenter, open-label, historical-controlled, single-arm transition study.

Centers

Subjects were recruited from 9 investigational sites located in Germany (3), Czech Republic (3), and Spain (3).

Objectives

The primary objective was to assess the safety and efficacy of changing to travoprost 0.004%/timolol 0.5% fixed combination from prior bimatoprost 0.03% and timolol 0.5% pharmacotherapy in patients with uncontrolled open-angle glaucoma or ocular hypertension.

Test Product, Dose, and Mode of Administration

Test product: Travoprost 0.004%/timolol 0.5% fixed combination
Dose: One drop each evening in qualifying eyes at 8:00 P.M.
Mode of administration: Topical ocular

Statistical Methods

If only one of a patient's eyes qualified for inclusion, this eye was selected for analysis. If both eyes qualified and were treated, then the worse evaluable eye (the eye with the higher intraocular pressure [IOP] at screening/baseline visit) was selected for analysis. If both eyes qualified and were treated, and both eyes had equal IOP at the screening/baseline visit, then the right eye was selected for analysis. Analyses were performed for both the ITT and PP data sets.

Study Population: Key Inclusion/Exclusion Criteria

Inclusion criteria:

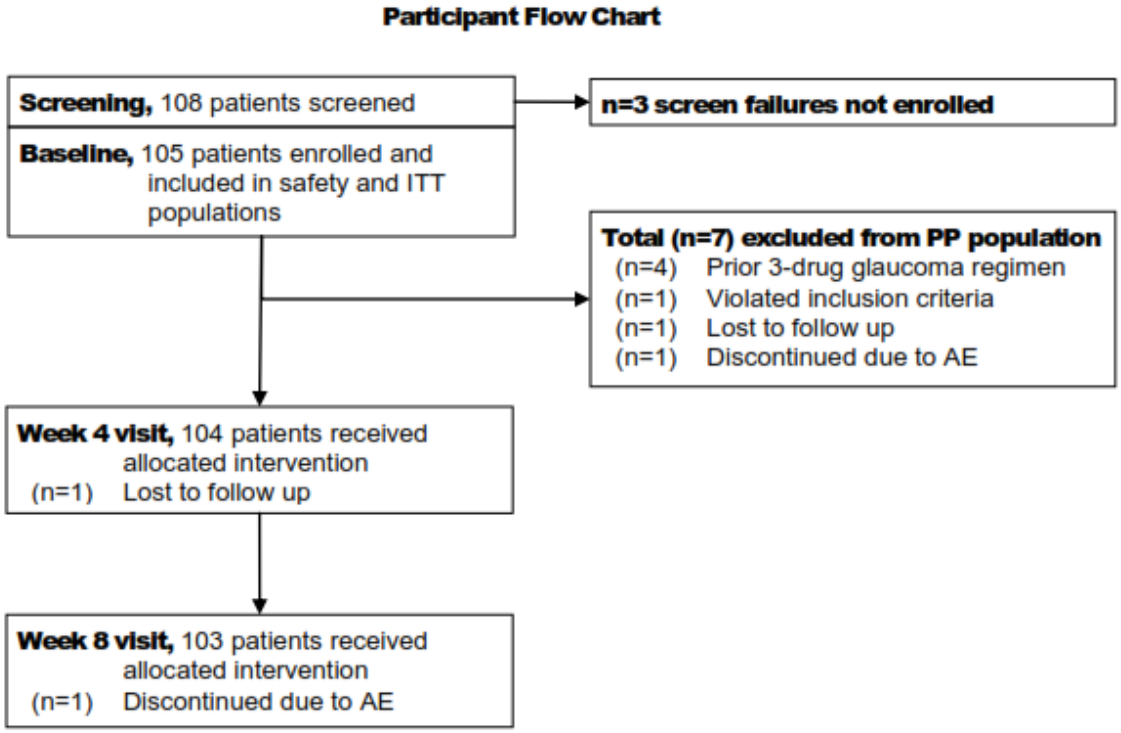
- Meets protocol-specified criteria for qualification and contraception
- Voluntarily consents to participate and provides written informed consent prior to any protocol-specific procedures

Exclusion criteria:

- Use of medications outside protocol-specified parameters
- Signs, symptoms or history of any condition that, per protocol or in the opinion of the investigator, might compromise:
  1. the safety or well-being of the participant or study staff

2. the safety or well-being of the participant's offspring (such as through breast-feeding)
3. the analysis of results

Participant Flow Table



Baseline Characteristics

Gender Demographic Statistics for ITT Population

Gender	Overall Participants
Female	62
Male	43

Age Demographic Statistics for ITT Population

Age (years)	Overall Participants
Mean (SD)	70.3 (10.7)
Range	37,91

Summary of Efficacy

Overall, the results of this study indicated that transition to travoprost 0.004%/timolol 0.5% fixed combination therapy (TTFC) produced a reduction in IOP for patients whose IOP was uncontrolled on bimatoprost and timolol therapy.

Primary Outcome Result(s)

Mean Intraocular Pressure at Screening/Baseline Visit and Week 8 Visit in Patients Receiving Prior Bimatoprost/Timolol Fixed Combination, Intent-to-treat Population

	Prior therapy Screening/Baseline n=79	Travoprost/timolol fixed combination Week 8 n=77	*P* value
Mean IOP ± standard deviation (mm Hg)	21.4 ± 2.6	18.1 ± 3.8	< .001

Secondary Outcome Result(s)

None reported.

Summary of Safety

Overall, travoprost/timolol was well tolerated in this patient population. Of the statistical analyses performed, no safety or tolerability outcomes demonstrated inferiority with travoprost/timolol compared with prior therapy.

Safety Results

Serious Adverse Events

One serious adverse event (AE) requiring hospitalization was reported (urinary tract infection preceded by itching) and was classified as unrelated to study medication. No deaths were reported.

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All Adverse Events by System Organ Class

Treatment-Emergent Adverse Events, Intent-to-treat Population

Treatment-emergent adverse event	n
Total	***28***
Ocular AEs	***22***
Ocular hyperemia	18
Ocular burning	1
Blurred vision	1
Foreign body sensation	1
Allergic reaction	1
Non-ocular AEs	***6***
Arthritis	1
Bronchitis	1
Pharyngitis	1
Urinary infection preceded by itching	1
Vertebral blockage	1
Vertigo	1

Other Relevant Findings

There are no other relevant findings to disclose.