Sponsor

Alcon Research, Ltd.

Generic Drug Name

Brinzolamide 1% /timolol 0.5%

Trial Indication(s)

Open-angle glaucoma
Ocular hypertension

Protocol Number

SMA-09-18

Protocol Title

Patient Preference Comparison of Azarga Versus Cosopt, After Single Doses in Patients With Open-Angled Glaucoma or Ocular Hypertension

Clinical Trial Phase

IV

Study Start/End Dates

13-SEP-2010 / 20-MAY-2011

Reason for Termination (if applicable)

Not applicable

Study Design/Methodology

This was a prospective, multicenter, patient-masked, randomized, interventional, crossover study.

Centers

Subjects were recruited from 6 investigational sites located in South America.

Objectives

The primary objective of this study was to assess patient preference for Brinzolamide/timolol (BTFC) or Dorzolamide/timolol (DTFC) after a single drop of each medication was administered to both eyes in patients with open-angle glaucoma or ocular hypertension.

Test Product, Dose, and Mode of Administration

Test product (Experimental): Brinzolamide/timolol (BFTC)
Dose: 1 drop in 1 eye (day 0) and 1 drop in each eye (both eyes) on either day 1 or day 2, based on randomized crossover assignment
Mode of administration: Topical ocular

Active comparator: Dorzolamide/timolol (DFTC)
Dose: 1 drop in 1 eye (day 0) and 1 drop in each eye (both eyes) on either day 1 or day 2, based on randomized crossover assignment
Mode of administration: Topical ocular

Statistical Methods

The criteria for evaluation included the Ocular Discomfort Scale (ODS), completed by the patient on both day 1 and day 2 within 1 minute of drop instillation, and the Preference Question, completed by the patient on day 2 after completing the ODS.

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

	BTFC	DTFC
Started	60	60
Safety population	60	60
Per protocol population	58	57
Completed	60	60

Baseline Characteristics

Continuous Age Demographic Statistics for ITT Population

	Mean (SD)	Range
BTFC	64.3 (13.4)	22 to 85
DTFC	65.8 (15.3)	19 to 89

Gender Demographic Statistics for ITT Population

Gender	BTFC	DTFC
Female	42	36
Male	18	24

Summary of Efficacy

A greater percentage of the PP population preferred BTFC compared with DTFC (67.0% versus 30.4%, respectively).

Primary Outcome Result

Patient preference for Study Medication on Day 2
Per protocol population (N=112)

Preference	N	%
BTFC	77	67.0
DTFC	35	30.4
No preference	3	2.6

Of the 115 patients in the PP population, 112 instilled both medications and expressed a study medication preference on day 2

Secondary Outcome Result(s)

None reported.

Summary of Safety

During this study, 7 subjects reported a total of 9 AEs. No serious AEs occurred during the study. All AEs reported during the study resolved without additional treatment and none of the AEs resulted in patient discontinuation from the study.

Safety Results

Serious Adverse Events by System Organ Class

No serious AEs occurred during the study.

Other Adverse Events by System Organ Class

Adverse Event Team	Number of subjects affected
Dry Throat	1
Flu	1
Bitter taste	3
Headache	3

Other Relevant Findings

There are no other relevant findings to disclose.

Date of Clinical Trial Report

31-May-2012