Abbreviated Novartis Clinical Trials Result Template

Sponsor

Alcon Research, Ltd.

Generic Drug Name

Brinzolamide 1%/brimonidine tartrate 0.2% ophthalmic suspension

Trial Indication(s)

Open-Angle Glaucoma
Ocular Hypertension

Protocol Number

C-10-039

Protocol Title

A Three-Month, Randomized, Double-Masked, Parallel-Group Study With a Planned Three-Month Safety Extension of the Efficacy and Safety of a Fixed Combination of Brinzolamide 1%/Brimonidine 0.2% Compared to Brinzolamide 1% and Brimonidine 0.2% All Dosed Three Times Daily in Patients With Open-Angle Glaucoma and/or Ocular Hypertension

Clinical Trial Study Phase

Phase 3

Study Start/End Dates

March 2011 to June 2012

Centers

Subjects were recruited and enrolled from 64 investigational centers in the United States.

Objectives

The purpose of this study is to evaluate the safety and efficacy of a new ophthalmic suspension (Brinz/Brim) in lowering intraocular pressure (IOP) relative to its individual active components in subjects with open-angle glaucoma and/or ocular hypertension.

Test Product (s), Dose(s), and Mode(s) of Administration

Brinzolamide 1%/brimonidine tartrate 0.2% ophthalmic suspension, 1 drop instilled in each eye 3 times a day for 3 months

Study Population: Key Inclusion/Exclusion Criteria

Inclusion Criteria:

- Sign Informed Consent document.
- At least 18 years of age.
- Diagnosis of open-angle glaucoma or ocular hypertension, with mean intraocular pressure within protocol-specified range at eligibility visit/s.
- Other protocol-specified inclusion criteria may apply.

Exclusion Criteria:

- Females of childbearing potential if pregnant, lactating, or not using highly effective birth control measures.
- Any form of glaucoma other than open-angle glaucoma.
- Severe central vision loss in either eye.
- Chronic, recurrent, or severe inflammatory eye disease.
- Ocular trauma within the preceding 6 months.
- Ocular infection or ocular inflammation within the preceding 3 months.
- Clinically significant or progressive retinal disease such as retinal degeneration, diabetic retinopathy, or retinal detachment.

- Best-corrected visual acuity score worse than 55 letters using the Early Treatment Diabetic Retinopathy Study chart.
- Other ocular pathology (including severe dry eye) that may, in the opinion of the Investigator, preclude the administration of study product.
- Ocular surgery within the preceding 6 months.
- Ocular laser surgery within the preceding 3 months.
- Any abnormality preventing reliable applanation tonometry.
- Any other conditions, including severe illness, which could make the subject, in the opinion of the Investigator, unsuitable for the study.
- Other protocol-specified exclusion criteria may apply.

For study results, refer to www.clinicaltrials.gov, NCT01297920.