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Trial record **1 of 1** for: C-10-040

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Brinzolamide/Brimonidine Twice a Day (BID) Fixed Combination (FC) vs Brinzolamide BID and Brimonidine BID in Patients With Open Angle Glaucoma or Ocular Hypertension

This study has been completed.

Sponsor:
Alcon Research

Information provided by (Responsible Party):
Alcon Research

ClinicalTrials.gov Identifier:
NCT01310777

First received: March 7, 2011
Last updated: January 24, 2014
Last verified: December 2013
History of Changes

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Results First Received: January 24, 2014

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Conditions:	Open-Angle Glaucoma Ocular Hypertension
Interventions:	Drug: Brinzolamide 1%/brimonidine tartrate 0.2% ophthalmic suspension Drug: Brinzolamide 1% ophthalmic suspension Drug: Brimonidine tartrate 0.2% 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
Subjects were recruited from 63 investigational centers in the Asia-Pacific region, the European Union, Latin America and Caribbean nations, and the United States.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
Of the 771 enrolled, 211 subjects did not meet inclusion/exclusion criteria and were exited from the study as screen failures prior to randomization. This reporting group includes all randomized subjects (560).

Reporting Groups

	Description
Brinz/Brim	Brinzolamide 1%/brimonidine tartrate 0.2% ophthalmic suspension, 1 drop instilled in each eye 2 times a day for 6 months
Brinz	Brinzolamide 1% ophthalmic suspension, 1 drop instilled in each eye 2 times a day for 6 months
Brim	Brimonidine tartrate 0.2% ophthalmic solution, 1 drop instilled in each eye 2 times a day for 6 months

Participant Flow: Overall Study

	Brinz/Brim	Brinz	Brim
STARTED	193	192	175
COMPLETED	160	178	145
NOT COMPLETED	33	14	30
Adverse Event	23	1	15
Lost to Follow-up	0	4	1
Patient's Decision Unrelated to AE	1	1	2
Inadequate Control of IOP	5	7	10
Other	4	1	2

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.
This reporting group includes all randomized subjects.

Reporting Groups

	Description
Brinz/Brim	Brinzolamide 1%/brimonidine tartrate 0.2% ophthalmic suspension, 1 drop instilled in each eye 2 times a day for 6 months
Brinz	Brinzolamide 1% ophthalmic suspension, 1 drop instilled in each eye 2 times a day for 6 months
Brim	Brimonidine tartrate 0.2% ophthalmic solution, 1 drop instilled in each eye 2 times a day for 6 months
Total	Total of all reporting groups

Baseline Measures

	Brinz/Brim	Brinz	Brim	Total
Number of Participants [units: participants]	193	192	175	560
Age, Customized [units: participants]				
<65 years	91	87	79	257
≥65 years	102	105	96	303
Gender [units: participants]				
Female	106	102	102	310
Male	87	90	73	250

Outcome Measures

1. Primary: Mean Diurnal IOP Change From Baseline at Month 3 [Time Frame: Baseline (Day 1), Month 3]

Hide Outcome Measure 1

Measure Type	Primary
Measure Title	Mean Diurnal IOP Change From Baseline at Month 3
Measure Description	Mean Diurnal IOP Change from Baseline at Month 3 (ie, the subject IOP change from baseline averaged over the 9 AM, + 2 h, and + 7 h time points at Month 3) was measured by Goldmann applanation tonometry. The study drug was instilled approximately 15 minutes after conducting the 9AM IOP measurement. One eye from each subject was chosen as the study eye, and only data for the study eye were used for the efficacy analysis. A higher IOP can be a greater risk factor for developing glaucoma or glaucoma progression (leading to optic nerve damage).
Time Frame	Baseline (Day 1), Month 3
Safety Issue	No

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.
The intent-to-treat (ITT) analysis set included all subjects who received study drug and completed at least 1 scheduled on-therapy study visit.

Reporting Groups

	Description
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Brinz	Brinzolamide 1% ophthalmic suspension, 1 drop instilled in each eye 2 times a day for 6 months
Brim	Brimonidine tartrate 0.2% ophthalmic solution, 1 drop instilled in each eye 2 times a day for 6 months

Measured Values

	Brinz/Brim	Brinz	Brim
Number of Participants Analyzed [units: participants]	**176**	**182**	**161**
Mean Diurnal IOP Change From Baseline at Month 3 [units: millimeters of mercury (mmHg)] Least Squares Mean (Standard Error)	**-7.9 (0.22)**	**-6.5 (0.23)**	**-6.4 (0.24)**

No statistical analysis provided for Mean Diurnal IOP Change From Baseline at Month 3

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Adverse events were collected for the duration of the study (1 year, 8 months). An AE was defined as any untoward medical occurrence in a subject who was administered a study medication, regardless of causal relationship with the medication.
Additional Description	This reporting group includes all subjects exposed to study drug. Reports of AEs were obtained through solicited and spontaneous comments from the study subjects, and through observations by the study Investigator as outlined in the study protocol.

Reporting Groups

	Description
Brinz/Brim	Brinzolamide 1%/brimonidine tartrate 0.2% ophthalmic suspension, 1 drop instilled in each eye 2 times a day for 6 months
Brinz	Brinzolamide 1% ophthalmic suspension, 1 drop instilled in each eye 2 times a day for 6 months
Brim	Brimonidine tartrate 0.2% ophthalmic solution, 1 drop instilled in each eye 2 times a day for 6 months

Serious Adverse Events

	Brinz/Brim	Brinz	Brim
Total, serious adverse events			
# participants affected / at risk	**5/193 (2.59%)**	**2/192 (1.04%)**	**3/175 (1.71%)**
Eye disorders			
Macular degeneration † 1			
# participants affected / at risk	**0/193 (0.00%)**	**0/192 (0.00%)**	**1/175 (0.57%)**
Hepatobiliary disorders			
Cholelithiasis † 1			
# participants affected / at risk	**1/193 (0.52%)**	**0/192 (0.00%)**	**0/175 (0.00%)**
Cholecystitis † 1			
# participants affected / at risk	**0/193 (0.00%)**	**1/192 (0.52%)**	**0/175 (0.00%)**
Infections and infestations			
Cellulitis † 1			
# participants affected / at risk	**1/193 (0.52%)**	**0/192 (0.00%)**	**0/175 (0.00%)**
Cystitis † 1			
# participants affected / at risk	**0/193 (0.00%)**	**0/192 (0.00%)**	**1/175 (0.57%)**
Injury, poisoning and procedural complications			
Vascular pseudoaneurysm † 1			
# participants affected / at risk	**1/193 (0.52%)**	**0/192 (0.00%)**	**0/175 (0.00%)**
Concussion † 1			
# participants affected / at risk	**0/193 (0.00%)**	**0/192 (0.00%)**	**1/175 (0.57%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Breast cancer † 1			
# participants affected / at risk	**1/193 (0.52%)**	**0/192 (0.00%)**	**0/175 (0.00%)**
Cervix carcinoma † 1			
# participants affected / at risk	**1/193 (0.52%)**	**0/192 (0.00%)**	**0/175 (0.00%)**
Pancreatic carcinoma † 1			
# participants affected / at risk	**1/193 (0.52%)**	**0/192 (0.00%)**	**0/175 (0.00%)**
Renal cell carcinoma † 1			
# participants affected / at risk	**1/193 (0.52%)**	**0/192 (0.00%)**	**0/175 (0.00%)**
Nervous system disorders			
Carotid artery occlusion † 1			
# participants affected / at risk	**0/193 (0.00%)**	**0/192 (0.00%)**	**1/175 (0.57%)**
Headache † 1			
# participants affected / at risk	**0/193 (0.00%)**	**0/192 (0.00%)**	**1/175 (0.57%)**
Renal and urinary disorders			
Calculus urethral † 1			
# participants affected / at risk	**0/193 (0.00%)**	**1/192 (0.52%)**	**0/175 (0.00%)**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA (13.0)

Other Adverse Events

Hide Other Adverse Events

Time Frame	Adverse events were collected for the duration of the study (1 year, 8 months). An AE was defined as any untoward medical occurrence in a subject who was administered a study medication, regardless of causal relationship with the medication.
Additional Description	This reporting group includes all subjects exposed to study drug. Reports of AEs were obtained through solicited and spontaneous comments from the study subjects, and through observations by the study Investigator as outlined in the study protocol.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
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Other Adverse Events

	Brinz/Brim	Brinz	Brim
Total, other (not including serious) adverse events			
# participants affected / at risk	**44/193 (22.80%)**	**12/192 (6.25%)**	**18/175 (10.29%)**
Eye disorders			
Ocular hyperaemia † 1			
# participants affected / at risk	**11/193 (5.70%)**	**3/192 (1.56%)**	**9/175 (5.14%)**
Conjunctivitis † 1			
# participants affected / at risk	**11/193 (5.70%)**	**2/192 (1.04%)**	**2/175 (1.14%)**
Vision Blurred † 1			
# participants affected / at risk	**11/193 (5.70%)**	**1/192 (0.52%)**	**3/175 (1.71%)**
Eye Pain † 1			
# participants affected / at risk	**11/193 (5.70%)**	**3/192 (1.56%)**	**0/175 (0.00%)**
Gastrointestinal disorders			
Dry Mouth † 1			
# participants affected / at risk	**7/193 (3.63%)**	**2/192 (1.04%)**	**9/175 (5.14%)**
Nervous system disorders			
Dysgeusia † 1			
# participants affected / at risk	**11/193 (5.70%)**	**4/192 (2.08%)**	**2/175 (1.14%)**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA (13.0)

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:** Sponsor reserves the right of prior review of any publication or presentation of information related to the study.

Results Point of Contact:

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No publications provided

Responsible Party:	Alcon Research
ClinicalTrials.gov Identifier:	NCT01310777 History of Changes
Other Study ID Numbers:	**C-10-040** 2010-024512-34 (EudraCT Number)
Study First Received:	March 7, 2011
Results First Received:	January 24, 2014
Last Updated:	January 24, 2014
Health Authority:	European Union: European Medicines Agency United States: Food and Drug Administration United States: Institutional Review Board Singapore: Institutional Review Board Germany: Ethics Commission Hungary: National Institute of Pharmacy Italy: Ethics Committee Lithuania: Bioethics Committee Latvia: Institutional Review Board Portugal: Ethics Committee for Clinical Research Spain: Comité Ético de Investigación Clínica United Kingdom: Research Ethics Committee Singapore: Domain Specific Review Boards Taiwan: Institutional Review Board Thailand: Ethical Committee Australia: Human Research Ethics Committee New Zealand: Health and Disability Ethics Committees