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Trial record **1 of 1** for: C-10-041

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Brinzolamide/Brimonidine Twice a Day (BID) Fixed Combination (FC) vs Brinzolamide BID Plus 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:
NCT01309204

First received: March 3, 2011
Last updated: March 7, 2014
Last verified: March 2014
History of Changes

Full Text View | Tabular View | Study Results | Disclaimer | How to Read a Study Record

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% fixed combination ophthalmic suspension Drug: Vehicle 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 102 investigational centers in the Asia-Pacific region, Canada, Central and South America, Europe, 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 1184 enrolled, 294 subjects did not meet inclusion/exclusion criteria and were exited from the study as screen failures prior to randomization. Of the 890 randomized, 2 subjects did not receive study medication. This reporting group includes all randomized subjects who received study medication (888), as treated.

Reporting Groups

	Description
Brinz/Brim	Vehicle, 1 drop instilled in each eye, followed by Brinzolamide 1%/brimonidine tartrate 0.2% fixed combination ophthalmic suspension, 1 drop instilled in each eye. A 10-minute waiting period separated the instillations. Study drugs were instilled twice a day for 6 months.

Brinz+Brim	Brimonidine tartrate 0.2% ophthalmic solution, 1 drop instilled in each eye, followed by Brinzolamide 1% ophthalmic suspension, 1 drop instilled in each eye. A 10-minute waiting period separated the instillations. Study drugs were instilled twice a day for 6 months.

Participant Flow: Overall Study

	Brinz/Brim	Brinz+Brim
STARTED	452	436
COMPLETED	385	361
NOT COMPLETED	67	75
Adverse Event	48	58
Lost to Follow-up	2	2
Subject's decision unrelated to an AE	9	10
Inadequate control of IOP	4	4
Other	4	1

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 subjects who received study medication, as treated.

Reporting Groups

	Description
Brinz/Brim	Vehicle, 1 drop instilled in each eye, followed by Brinzolamide 1%/brimonidine tartrate 0.2% fixed combination ophthalmic suspension, 1 drop instilled in each eye. A 10-minute waiting period separated the instillations. Study drugs were instilled twice a day for 6 months.
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Total	Total of all reporting groups

Baseline Measures

	Brinz/Brim	Brinz+Brim	Total
Number of Participants [units: participants]	452	436	888
Age, Customized [units: participants]			
<65 years	227	211	438
≥ 65 years	225	225	450
Gender [units: participants]			
Female	252	246	498
Male	200	190	390

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 and + 2 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.
Per Protocol (PP): All subjects who received study medication, satisfied prerandomization inclusion/exclusion criteria, and completed at least 1 scheduled on-therapy study visit. In addition, individual subject visits and data points that did not satisfy the protocol criteria may have been excluded.

Reporting Groups

	Description
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Measured Values

	Brinz/Brim	Brinz+Brim
Number of Participants Analyzed [units: participants]	**384**	**373**
Mean Diurnal IOP Change From Baseline at Month 3 [units: millimeters of mercury (mmHg)] Least Squares Mean (Standard Error)	**-8.5 (0.16)**	**-8.3 (0.16)**

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 (AE) were collected for the duration of the study (1 year, 8 months). An AE was defined as any untoward medical occurrence in a subject that was administered a study medication, regardless of causal relationship with the medication.
Additional Description	This reporting group includes all subjects who received study medication, as treated. 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	Vehicle, 1 drop instilled in each eye, followed by Brinzolamide 1%/brimonidine tartrate 0.2% fixed combination ophthalmic suspension, 1 drop instilled in each eye. A 10-minute waiting period separated the instillations. Study drugs were instilled twice a day for 6 months.
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Serious Adverse Events

	Brinz/Brim	Brinz+Brim
Total, serious adverse events		
# participants affected / at risk	**11/452 (2.43%)**	**8/436 (1.83%)**
Cardiac disorders		
Aortic valve incompetence † 1		
# participants affected / at risk	**1/452 (0.22%)**	**0/436 (0.00%)**
Atrial fibrillation † 1		
# participants affected / at risk	**0/452 (0.00%)**	**1/436 (0.23%)**
Myocardial infarction † 1		
# participants affected / at risk	**0/452 (0.00%)**	**1/436 (0.23%)**
Ear and labyrinth disorders		
Vertigo † 1		
# participants affected / at risk	**1/452 (0.22%)**	**0/436 (0.00%)**
Eye disorders		
Corneal erosion † 1		
# participants affected / at risk	**2/452 (0.44%)**	**0/436 (0.00%)**
Hepatobiliary disorders		
Cholecystitis † 1		
# participants affected / at risk	**0/452 (0.00%)**	**1/436 (0.23%)**
Infections and infestations		
Kidney infection † 1		
# participants affected / at risk	**1/452 (0.22%)**	**0/436 (0.00%)**
Pneumonia primary atypical † 1		
# participants affected / at risk	**0/452 (0.00%)**	**1/436 (0.23%)**
Investigations		
Arthroscopy † 1		
# participants affected / at risk	**1/452 (0.22%)**	**0/436 (0.00%)**
Prostatic specific antigen increased † 1		
# participants affected / at risk	**1/452 (0.22%)**	**0/436 (0.00%)**
Musculoskeletal and connective tissue disorders		
Spinal osteoarthritis † 1		
# participants affected / at risk	**1/452 (0.22%)**	**0/436 (0.00%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Renal cell carcinoma † 1		
# participants affected / at risk	**1/452 (0.22%)**	**0/436 (0.00%)**

Uterine cancer † 1		
# participants affected / at risk	**0/452 (0.00%)**	**1/436 (0.23%)**
Nervous system disorders		
Headache † 1		
# participants affected / at risk	**1/452 (0.22%)**	**0/436 (0.00%)**
Neuropathy peripheral † 1		
# participants affected / at risk	**1/452 (0.22%)**	**0/436 (0.00%)**
Respiratory, thoracic and mediastinal disorders		
Pulmonary embolism † 1		
# participants affected / at risk	**0/452 (0.00%)**	**1/436 (0.23%)**
Sleep apnoea syndrome † 1		
# participants affected / at risk	**0/452 (0.00%)**	**1/436 (0.23%)**
Surgical and medical procedures		
Finger amputation † 1		
# participants affected / at risk	**1/452 (0.22%)**	**0/436 (0.00%)**
Mastectomy † 1		
# participants affected / at risk	**1/452 (0.22%)**	**0/436 (0.00%)**
Vascular disorders		
Venous occlusion † 1		
# participants affected / at risk	**0/452 (0.00%)**	**1/436 (0.23%)**

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

Other Adverse Events

Hide Other Adverse Events

Time Frame	Adverse events (AE) were collected for the duration of the study (1 year, 8 months). An AE was defined as any untoward medical occurrence in a subject that was administered a study medication, regardless of causal relationship with the medication.
Additional Description	This reporting group includes all subjects who received study medication, as treated. 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	**0/452 (0.00%)**	**0/436 (0.00%)**

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 by Alcon Research

Publications automatically indexed to this study:

Gandolfi SA, Lim J, Sanseau AC, Parra Restrepo JC, Hamacher T. Randomized trial of brinzolamide/brimonidine versus brinzolamide plus brimonidine for open-angle glaucoma or ocular hypertension. Adv Ther. 2014 Dec;31(12):1213-27. doi: 10.1007/s12325-014-0168-y. Epub 2014 Nov 28.

Responsible Party:	Alcon Research
ClinicalTrials.gov Identifier:	NCT01309204 History of Changes
Other Study ID Numbers:	**C-10-041** 2010-024513-31 (EudraCT Number)
Study First Received:	March 3, 2011
Results First Received:	January 24, 2014
Last Updated:	March 7, 2014
Health Authority:	European Union: European Medicines Agency United States: Food and Drug Administration United States: Institutional Review Board

Argentina: Human Research Bioethics Committee
Australia: Human Research Ethics Committee
Austria: Ethikkommission
Belgium: Ethics Committee
Brazil: National Committee of Ethics in Research
Canada: Ethics Review Committee
France: Committee for the Protection of Personnes
Germany: Ethics Commission
Hungary: Research Ethics Medical Committee
India: Institutional Review Board
Italy: Ethics Committee
Lithuania: Bioethics Committee
Netherlands: Medical Ethics Review Committee (METC)
New Zealand: Ethics Committee
Poland: Ethics Committee
Portugal: Ethics Committee for Clinical Research
Spain: Comité Ético de Investigación Clínica
Sweden: Regional Ethical Review Board
United Kingdom: Research Ethics Committee