ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: 03/13/2013

ClinicalTrials.gov ID: NCT00972374

Study Identification

Unique Protocol ID:	190342-031D
Brief Title:	Safety and Efficacy of Brimonidine Tartrate Posterior Segment Drug Delivery System in Improving Visual Function
Official Title:	
Secondary IDs:	

Study Status

Record Verification:	March 2013
Overall Status:	Completed
Study Start:	November 2009
Primary Completion:	October 2010 [Actual]
Study Completion:	July 2011 [Actual]

Sponsor/Collaborators

Sponsor:	Allergan
Responsible Party:	Sponsor
Collaborators:	

Oversight

FDA Regulated?:	Yes
Applicable Trial?:	Section 801 Clinical Trial? Yes Delayed Posting? No

IND/IDE Protocol?:	Yes
IND/IDE Information:	Grantor: CDER IND/IDE Number: 70,503 Serial Number: Has Expanded Access? No
Review Board:	Approval Status: Board Name: Board Affiliation: Phone: Email:
Data Monitoring?:	Yes
Plan to Share Data?:	
Oversight Authorities:	United States: Food and Drug Administration

Study Description

Brief Summary:	This study will evaluate the efficacy and safety of the Brimo PS DDS® Applicator System (200 µg and 400 µg brimonidine tartrate) on visual function in patients with previous rhegmatogenous macula-off retinal detachment.
Detailed Description:	

Conditions

Conditions:	Rhegmatogenous Macula-off Retinal Detachment
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 2
Intervention Model:	Parallel Assignment
Number of Arms:	3
Masking:	Double Blind (Subject, Caregiver, Outcomes Assessor)
Allocation:	Randomized

Endpoint Classification: Safety/Efficacy Study

Enrollment: 44 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: 400 ug Brimonidine Implant 400 ug Brimonidine Tartrate Posterior Segment Drug Delivery system on Day 1 in the study eye.	Drug: 400 ug Brimonidine Implant 400 ug Brimonidine Tartrate Posterior Segment Drug Delivery system on Day 1 in the study eye. Other Names: • Brimonidine Tartrate PS DDS®
Experimental: 200 ug Brimonidine Implant 200 ug Brimonidine Tartrate Posterior Segment Drug Delivery system on Day 1 in the study eye.	Drug: 200 ug Brimonidine Implant 200 ug Brimonidine Tartrate Posterior Segment Drug Delivery system on Day 1 in the study eye. Other Names: • Brimonidine Tartrate PS DDS®
Sham Comparator: Sham (no implant) Sham Posterior Segment Drug Delivery system on Day 1 in the study eye.	Sham (no implant) Sham Posterior Segment Drug Delivery system on Day 1 in the study eye.

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 18 Years

Maximum Age:

Gender: Both

Accepts Healthy Volunteers?: No

Criteria: Inclusion Criteria:

- The macula-off retinal detachment must have been caused by a rupture (rhegmatogenous in etiology)
- The repair of the macula-off retinal detachment must have occurred at least 6 months before the Day 1 visit in the study eye
- The repair must have been deemed an anatomic success and required no more than one macular re-attachment procedure
- The visual acuity score must be between 20/50 and 20/320 in the study eye

Exclusion Criteria:

- Any sight-threatening ocular condition in the study eye other than the ruptured retinal detachment

- Anticipated need for ocular surgery during the 12-month study period
- Any injectable, periocular, or intravitreal corticosteroid treatment to study eye within 6 months prior to screening (eg, triamcinolone acetonide)
- Any injectable, periocular, or intravitreal anti-VEGF treatment to the study eye within 3 months prior to screening (eg, Avastin or Lucentis)
- Any infectious condition in the study eye

Contacts/Locations

Study Officials: Medical Director
Study Director
Allergan, Inc.

Locations: United States, Texas
Abilene, Texas, United States

Italy
Milan, Italy

United Kingdom
London, United Kingdom

Israel
Tel Aviv, Israel

India
Chennai, India

Australia
Sydney, Australia

Korea, Republic of
Seoul, Korea, Republic of

Philippines
Makati, Philippines

India
New Delhi, India

References

Citations:

Links:

Study Data/Documents:

Study Results

Participant Flow

Reporting Groups

	Description
400 ug Brimonidine Implant	400 ug Brimonidine Tartrate Posterior Segment Drug Delivery system on Day 1 in the study eye.
200 ug Brimonidine Implant	200 ug Brimonidine Tartrate Posterior Segment Drug Delivery system on Day 1 in the study eye.
Sham (no Implant)	Sham Posterior Segment Drug Delivery system on Day 1 in the study eye.

Overall Study

	400 ug Brimonidine Implant	200 ug Brimonidine Implant	Sham (no Implant)
Started	15	15	14
Completed	13	15	13
Not Completed	2	0	1

Baseline Characteristics

Reporting Groups

	Description
400 ug Brimonidine Implant	400 ug Brimonidine Tartrate Posterior Segment Drug Delivery system on Day 1 in the study eye.
200 ug Brimonidine Implant	200 ug Brimonidine Tartrate Posterior Segment Drug Delivery system on Day 1 in the study eye.
Sham (no Implant)	Sham Posterior Segment Drug Delivery system on Day 1 in the study eye.

Baseline Measures

	400 ug Brimonidine Implant	200 ug Brimonidine Implant	Sham (no Implant)	Total
Number of Participants	15	15	14	44

	400 ug Brimonidine Implant	200 ug Brimonidine Implant	Sham (no Implant)	Total
Age, Continuous [units: Years] Mean (Standard Deviation)	54.2 (17.12)	54.3 (20.36)	56.1 (15.19)	54.9 (17.35)
Gender, Male/Female [units: Participants]				
Female	6	5	5	16
Male	9	10	9	28

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Percentage of Patients With at Least a 15-Letter Increase From Baseline in Best Corrected Visual Acuity (BCVA) in the Study Eye
Measure Description	BCVA is measured using an eye chart and is reported as the number of letters read correctly (ranging from 0 to 100 letters). The lower the number of letters read correctly on the eye chart, the worse the vision (or visual acuity). An increase in the number of letters read correctly indicates that vision has improved. The percentage of patients with at least a 15-letter increase in BCVA in the study eye is reported.
Time Frame	Month 3
Safety Issue?	No

Analysis Population Description

Intent to Treat: all randomized patients

Reporting Groups

	Description
400 ug Brimonidine Implant	400 ug Brimonidine Tartrate Posterior Segment Drug Delivery system on Day 1 in the study eye.
200 ug Brimonidine Implant	200 ug Brimonidine Tartrate Posterior Segment Drug Delivery system on Day 1 in the study eye.
Sham (no Implant)	Sham Posterior Segment Drug Delivery system on Day 1 in the study eye.

Measured Values

	400 ug Brimonidine Implant	200 ug Brimonidine Implant	Sham (no Implant)
Number of Participants Analyzed	15	15	14
Percentage of Patients With at Least a 15-Letter Increase From Baseline in Best Corrected Visual Acuity (BCVA) in the Study Eye	6.7	6.7	0

	400 ug Brimonidine Implant	200 ug Brimonidine Implant	Sham (no Implant)
[units: Percentage of Patients]			

2. Secondary Outcome Measure:

Measure Title	Change From Baseline in Best Corrected Visual Acuity (BCVA) in the Study Eye
Measure Description	BCVA is measured using an eye chart and is reported as the number of letters read correctly (ranging from 0 to 100 letters) in the study eye. The lower the number of letters read correctly on the eye chart, the worse the vision (or visual acuity). A positive change from baseline indicates an improvement and a negative change from baseline indicates a worsening.
Time Frame	Baseline, Month 3
Safety Issue?	No

Analysis Population Description

Intent to Treat: all randomized patients

Reporting Groups

	Description
400 ug Brimonidine Implant	400 ug Brimonidine Tartrate Posterior Segment Drug Delivery system on Day 1 in the study eye.
200 ug Brimonidine Implant	200 ug Brimonidine Tartrate Posterior Segment Drug Delivery system on Day 1 in the study eye.
Sham (no Implant)	Sham Posterior Segment Drug Delivery system on Day 1 in the study eye.

Measured Values

	400 ug Brimonidine Implant	200 ug Brimonidine Implant	Sham (no Implant)
Number of Participants Analyzed	15	15	14
Change From Baseline in Best Corrected Visual Acuity (BCVA) in the Study Eye [units: Number of Letters Read Correctly] Mean (Standard Deviation)			
Baseline	46.6 (13.69)	53.3 (8.46)	50.3 (10.92)
Change from Baseline at Month 3	6.0 (6.23)	3.1 (6.78)	4.8 (4.64)

3. Other Pre-specified Outcome Measure:

Measure Title	Percentage of Patients With Intraocular Pressure (IOP) < 10 mmHg in the Study Eye at Any Follow up Visit
Measure Description	IOP is the fluid pressure inside the eye. The percentage of patients with IOP < 10 millimeters of mercury (mmHg) in the study eye at any follow up visit is presented.
Time Frame	12 Months
Safety Issue?	No

Analysis Population Description

Intent to Treat: all randomized patients

Reporting Groups

	Description
400 ug Brimonidine Implant	400 ug Brimonidine Tartrate Posterior Segment Drug Delivery system on Day 1 in the study eye.
200 ug Brimonidine Implant	200 ug Brimonidine Tartrate Posterior Segment Drug Delivery system on Day 1 in the study eye.
Sham (no Implant)	Sham Posterior Segment Drug Delivery system on Day 1 in the study eye.

Measured Values

	400 ug Brimonidine Implant	200 ug Brimonidine Implant	Sham (no Implant)
Number of Participants Analyzed	15	15	14
Percentage of Patients With Intraocular Pressure (IOP) < 10 mmHg in the Study Eye at Any Follow up Visit [units: Percentage of Patients]	20.0	26.7	28.6

Reported Adverse Events

Time Frame	[Not specified]
Additional Description	For Ocular Adverse Events (AEs), only those in the study eye are reported in the "Other Adverse Events" section. For Serious Adverse Events (SAEs), all ocular events are reported in the SAE section, regardless of the eye.

Reporting Groups

	Description
400 ug Brimonidine Implant	400 ug Brimonidine Tartrate Posterior Segment Drug Delivery system on Day 1 in the study eye.
200 ug Brimonidine Implant	200 ug Brimonidine Tartrate Posterior Segment Drug Delivery system on Day 1 in the study eye.
Sham (no Implant)	Sham Posterior Segment Drug Delivery system on Day 1 in the study eye.

Serious Adverse Events

	400 ug Brimonidine Implant	200 ug Brimonidine Implant	Sham (no Implant)
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	0/15 (0%)	2/15 (13.33%)	2/14 (14.29%)
Cardiac disorders			
Myocardial Infarction [A] †	0/15 (0%)	0/15 (0%)	1/14 (7.14%)
Gastrointestinal disorders			
Haemorrhoids [A] †	0/15 (0%)	1/15 (6.67%)	0/14 (0%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Prostate Cancer [y] [A] †	0/9 (0%)	1/10 (10%)	0/9 (0%)
Surgical and medical procedures			
Strabismus Correction [A] †	0/15 (0%)	0/15 (0%)	1/14 (7.14%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA version 14.0

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	400 ug Brimonidine Implant	200 ug Brimonidine Implant	Sham (no Implant)
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	7/15 (46.67%)	12/15 (80%)	9/14 (64.29%)
Cardiac disorders			
Arrhythmia [A] †	0/15 (0%)	0/15 (0%)	1/14 (7.14%)
Myocardial Infarction [A] †	0/15 (0%)	0/15 (0%)	1/14 (7.14%)
Eye disorders			

	400 ug Brimonidine Implant	200 ug Brimonidine Implant	Sham (no Implant)
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Anterior Chamber Inflammation [A] †	0/15 (0%)	1/15 (6.67%)	0/14 (0%)
Cataract Nuclear [A] †	1/15 (6.67%)	0/15 (0%)	0/14 (0%)
Cataract Subscapular [A] †	1/15 (6.67%)	1/15 (6.67%)	0/14 (0%)
Conjunctival Granuloma [A] †	0/15 (0%)	0/15 (0%)	1/14 (7.14%)
Conjunctival Haemorrhage [A] †	3/15 (20%)	1/15 (6.67%)	2/14 (14.29%)
Conjunctival Hyperaemia [A] †	2/15 (13.33%)	1/15 (6.67%)	1/14 (7.14%)
Conjunctival Oedema [A] *	1/15 (6.67%)	1/15 (6.67%)	1/14 (7.14%)
Conjunctivitis [A] †	1/15 (6.67%)	0/15 (0%)	0/14 (0%)
Corneal Erosion [A] †	0/15 (0%)	1/15 (6.67%)	0/14 (0%)
Dry Eye [A] *	0/15 (0%)	0/15 (0%)	1/14 (7.14%)
Episcleritis [A] †	0/15 (0%)	0/15 (0%)	1/14 (7.14%)
Eye Irritation [A] *	1/15 (6.67%)	0/15 (0%)	0/14 (0%)
Eye Pain [A] *	1/15 (6.67%)	3/15 (20%)	1/14 (7.14%)
Eye Pruritus [A] †	2/15 (13.33%)	0/15 (0%)	0/14 (0%)
Eyelid Cyst [A] †	0/15 (0%)	1/15 (6.67%)	0/14 (0%)
Eyelid Ptosis [A] †	0/15 (0%)	0/15 (0%)	1/14 (7.14%)
Hypotony of Eye [A] †	1/15 (6.67%)	2/15 (13.33%)	0/14 (0%)
Iridocyclitis [A] †	0/15 (0%)	0/15 (0%)	1/14 (7.14%)
Iritis [A] †	0/15 (0%)	1/15 (6.67%)	0/14 (0%)
Keratoconjunctivitis Sicca [A] †	1/15 (6.67%)	0/15 (0%)	0/14 (0%)
Macular Oedema [A] †	0/15 (0%)	0/15 (0%)	1/14 (7.14%)
Maculopathy [A] †	1/15 (6.67%)	1/15 (6.67%)	0/14 (0%)

	400 ug Brimonidine Implant	200 ug Brimonidine Implant	Sham (no Implant)
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Optic Atrophy [A] †	1/15 (6.67%)	0/15 (0%)	0/14 (0%)
Optic Disc Haemorrhage [A] †	1/15 (6.67%)	0/15 (0%)	0/14 (0%)
Posterior Capsule Opacification [A] †	0/15 (0%)	1/15 (6.67%)	0/14 (0%)
Retinal Aneurysm [A] †	0/15 (0%)	0/15 (0%)	1/14 (7.14%)
Retinal Degeneration [A] †	0/15 (0%)	1/15 (6.67%)	0/14 (0%)
Retinal Depigmentation [A] †	0/15 (0%)	1/15 (6.67%)	0/14 (0%)
Retinal Haemorrhage [A] †	1/15 (6.67%)	0/15 (0%)	1/14 (7.14%)
Scleral Disorder [A] †	0/15 (0%)	0/15 (0%)	1/14 (7.14%)
Vision Blurred [A] *	0/15 (0%)	1/15 (6.67%)	1/14 (7.14%)
Visual Impairment [A] *	0/15 (0%)	1/15 (6.67%)	0/14 (0%)
Vitreous Disorder [A] †	0/15 (0%)	1/15 (6.67%)	0/14 (0%)
Vitreous Floaters [A] *	1/15 (6.67%)	0/15 (0%)	1/14 (7.14%)
Vitreous Haemorrhage [A] †	1/15 (6.67%)	0/15 (0%)	0/14 (0%)
Vitreous Opacities [A] †	0/15 (0%)	1/15 (6.67%)	0/14 (0%)
Gastrointestinal disorders			
Abdominal Pain Lower [A] *	1/15 (6.67%)	0/15 (0%)	0/14 (0%)
Dyspepsia [A] *	0/15 (0%)	1/15 (6.67%)	0/14 (0%)
Haemorrhoids [A] *	0/15 (0%)	1/15 (6.67%)	0/14 (0%)
Nausea [A] *	0/15 (0%)	0/15 (0%)	1/14 (7.14%)
General disorders			
Influenza Like Illness [A] *	1/15 (6.67%)	0/15 (0%)	0/14 (0%)
Immune system disorders			

	400 ug Brimonidine Implant	200 ug Brimonidine Implant	Sham (no Implant)
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Seasonal Allergy [A] *	0/15 (0%)	1/15 (6.67%)	0/14 (0%)
Infections and infestations			
Cholecystitis Infective [A] †	0/15 (0%)	1/15 (6.67%)	0/14 (0%)
Cystitis [A] †	0/15 (0%)	1/15 (6.67%)	0/14 (0%)
Herpes Zoster [A] *	0/15 (0%)	0/15 (0%)	1/14 (7.14%)
Hordeolum [A] *	0/15 (0%)	0/15 (0%)	1/14 (7.14%)
Pharyngitis Streptococcal [A] †	0/15 (0%)	1/15 (6.67%)	0/14 (0%)
Pneumonia [A] †	1/15 (6.67%)	0/15 (0%)	0/14 (0%)
Tooth Abscess [A] †	0/15 (0%)	0/15 (0%)	1/14 (7.14%)
Tooth Infection [A] †	0/15 (0%)	0/15 (0%)	1/14 (7.14%)
Injury, poisoning and procedural complications			
Head Injury [A] *	0/15 (0%)	1/15 (6.67%)	0/14 (0%)
Investigations			
Intraocular Pressure Decreased [A] †	1/15 (6.67%)	2/15 (13.33%)	0/14 (0%)
Metabolism and nutrition disorders			
Hypercholesterolaemia [A] †	0/15 (0%)	0/15 (0%)	1/14 (7.14%)
Musculoskeletal and connective tissue disorders			
Pain in Extremity [A] *	1/15 (6.67%)	0/15 (0%)	0/14 (0%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Prostate Cancer [A] †	0/9 (0%)	1/10 (10%)	0/9 (0%)
Psychiatric disorders			
Depression [A] †	0/15 (0%)	2/15 (13.33%)	0/14 (0%)
Renal and urinary disorders			

	400 ug Brimonidine Implant	200 ug Brimonidine Implant	Sham (no Implant)
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Hypertonic Bladder [A] †	0/15 (0%)	1/15 (6.67%)	0/14 (0%)
Renal Mass [A] †	0/15 (0%)	1/15 (6.67%)	0/14 (0%)
Skin and subcutaneous tissue disorders			
Hyperhidrosis [A] *	0/15 (0%)	0/15 (0%)	1/14 (7.14%)
Surgical and medical procedures			
Strabismus Correction [A] †	0/15 (0%)	0/15 (0%)	1/14 (7.14%)

† Indicates events were collected by systematic assessment.
* Indicates events were collected by non-systematic methods.
A Term from vocabulary, MedDRA version 14.0

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

A 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 90 days from the time submitted to the sponsor for review. The sponsor cannot require changes to the communication and cannot extend the embargo.

Results Point of Contact:

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