ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: 03/11/2011

ClinicalTrials.gov ID: NCT00333814

Study Identification

Unique Protocol ID:	206207-014
Brief Title:	A Study of the Safety and Efficacy of a New Treatment for Non-Infectious Intermediate or Posterior Uveitis
Official Title:	
Secondary IDs:	

Study Status

Record Verification:	March 2011
Overall Status:	Completed
Study Start:	May 2006
Primary Completion:	December 2008 [Actual]
Study Completion:	April 2009 [Actual]

Sponsor/Collaborators

Sponsor:	Allergan
Responsible Party:	
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: 58,663 Serial Number: Has Expanded Access? No
Review Board:	Approval Status: Board Name: Board Affiliation: Phone: Email:
Data Monitoring?:	
Plan to Share Data?:	
Oversight Authorities:	United States: Food and Drug Administration

Study Description

Brief Summary:	This study will evaluate the safety and efficacy of an intravitreal implant of dexamethasone for the treatment of non-infectious intermediate or posterior uveitis.
Detailed Description:	

Conditions

Conditions:	Intermediate Uveitis Posterior Uveitis
Keywords:	

Study Design

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

Endpoint Classification: Safety/Efficacy Study

Enrollment: 229 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Active Comparator: 1 Dexamethasone 350 µg	Drug: Dexamethasone Dexamethasone 350 µg; injection drug delivery system at Day 0 Other Names: • Posurdex®
Active Comparator: 2 Dexamethasone 700 µg	Drug: dexamethasone Dexamethasone 700 µg injection drug delivery system at Day 0 Other Names: • Posurdex®
Sham Comparator: 3 Sham	Drug: Sham injection Sham injection at Day 0

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 18 Years

Maximum Age:

Gender: Both

Accepts Healthy Volunteers?: No

Criteria: Inclusion Criteria:

- 18 years or older with a diagnosis of chronic intermediate uveitis in at least one eye

Exclusion Criteria:

- Uncontrolled systemic disease
- Any active ocular infections

Contacts/Locations

Study Officials: Medical Director
Study Director
Allergan, Inc.

Locations: United States, Texas
Dallas, Texas, United States

Canada, Quebec
Montreal, Quebec, Canada

Brazil
São Paulo, São Paulo/SP, Brazil

United Kingdom
London, United Kingdom

France
Paris, France

Belgium
Antwerp, Belgium

Germany
Heidelberg, Germany

Spain
Madrid, Spain

Portugal
Coimbra, Portugal

Switzerland
Lausanne, Switzerland

Czech Republic
Prague, Czech Republic

Poland
Gdansk, Poland

Austria
Vienna, Austria

Greece
Holargos, Greece

Israel
Petah Tikva, Israel

South Africa
Johannesburg, South Africa

Korea, Republic of
Seoul, Korea, Republic of

Singapore
Singapore, Singapore

Australia
Sydney, Australia

India
Hyderabad, India

Italy
Padova, Italy

References

Citations:

Links: URL: http://www.allerganclinicaltrials.com/inquiries/trialsubject.aspx
Description Related Info

Study Data/Documents:

Study Results

Participant Flow

Reporting Groups

	Description
Dexamethasone 350 µg	Dexamethasone 350 µg

	Description
Dexamethasone 700 µg	Dexamethasone 700 µg
Sham	Sham

Overall Study

	Dexamethasone 350 µg	Dexamethasone 700 µg	Sham
Started	76	77	76
Completed	73	73	71
Not Completed	3	4	5

Baseline Characteristics

Reporting Groups

	Description
Dexamethasone 350 µg	Dexamethasone 350 µg
Dexamethasone 700 µg	Dexamethasone 700 µg
Sham	Sham

Baseline Measures

	Dexamethasone 350 µg	Dexamethasone 700 µg	Sham	Total
Number of Participants	76	77	76	229
Age, Customized [units: Participants]				
<45 years	39	43	41	123
Between 45 and 65 years	32	28	27	87
>65 years	5	6	8	19
Gender, Male/Female [units: participants]				
Female	48	46	51	145
Male	28	31	25	84

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Percentage of Patients With Vitreous Haze (Ocular Inflammation) Score of Zero
Measure Description	Percentage of patients with Vitreous Haze Score of Zero at Week 8. Score is based on standardized scale of 0 to +4 where 0 equals no inflammation and +4 equals optic nerve head not visible (severe).
Time Frame	Week 8
Safety Issue?	No

Analysis Population Description
Intent to Treat

Reporting Groups

	Description
Dexamethasone 350 µg	Dexamethasone 350 µg
Dexamethasone 700 µg	Dexamethasone 700 µg
Sham	Sham

Measured Values

	Dexamethasone 350 µg	Dexamethasone 700 µg	Sham
Number of Participants Analyzed	76	77	76
Percentage of Patients With Vitreous Haze (Ocular Inflammation) Score of Zero [units: Percentage of Patients]	35.5	46.8	11.8

2. Other Pre-specified Outcome Measure:

Measure Title	Percentage of Patients With at Least a 15-Letter Improvement in Best Corrected Visual Acuity (BCVA)
Measure Description	Percentage of Patients with at least a 15-letter improvement in BCVA at Week 8 from Baseline. 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). The higher the number of letters read correctly, the better the vision (or visual acuity). An improvement in the number of letters read means that the vision has improved.
Time Frame	Week 8

Safety Issue?	No

Analysis Population Description
Intent to Treat

Reporting Groups

	Description
Dexamethasone 350 µg	Dexamethasone 350 µg
Dexamethasone 700 µg	Dexamethasone 700 µg
Sham	Sham

Measured Values

	Dexamethasone 350 µg	Dexamethasone 700 µg	Sham
Number of Participants Analyzed	76	77	76
Percentage of Patients With at Least a 15-Letter Improvement in Best Corrected Visual Acuity (BCVA) [units: Percentage of Patients]	39.5	42.9	6.6

3. Other Pre-specified Outcome Measure:

Measure Title	Percentage of Patients With at Least a 10-Point Improvement in the National Eye Institute Visual Functioning Questionnaire-25 (NEI-VFQ-25)Score
Measure Description	Percentage of patients with at least a 10-Point Improvement in the NEI-VFQ-25 over-all composite score at Week 8 from Baseline. The NEI-VFQ-25 consists of 25 vision-targeted questions plus one general health question resulting in a score of 0-100 (100 represents best functionality).
Time Frame	Week 8
Safety Issue?	No

Analysis Population Description
Intent to Treat

Reporting Groups

	Description
Dexamethasone 350 µg	Dexamethasone 350 µg
Dexamethasone 700 µg	Dexamethasone 700 µg

	Description
Sham	Sham

Measured Values

	Dexamethasone 350 µg	Dexamethasone 700 µg	Sham
Number of Participants Analyzed	76	77	76
Percentage of Patients With at Least a 10-Point Improvement in the National Eye Institute Visual Functioning Questionnaire-25 (NEI-VFQ-25)Score [units: Percentage of Patients]	40.8	50.7	15.9

Reported Adverse Events

Time Frame	[Not specified]
Additional Description	The safety population was used to calculate the number of participants at risk for SAEs and AEs and is the total number of patients that were randomized AND treated. The Intent-to-Treat population was used for the outcome measure analyses and is calculated as the number of patients that were randomized (or started the study).

Reporting Groups

	Description
Dexamethasone 350 µg	Dexamethasone 350 µg
Dexamethasone 700 µg	Dexamethasone 700 µg
Sham	Sham

Serious Adverse Events

	Dexamethasone 350 µg	Dexamethasone 700 µg	Sham
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	6/74 (8.11%)	7/76 (9.21%)	5/75 (6.67%)
Eye disorders			
Cataract [A] †	1/74 (1.35%)	0/76 (0%)	1/75 (1.33%)

	Dexamethasone 350 µg	Dexamethasone 700 µg	Sham
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Endophthalmitis [A] †	0/74 (0%)	1/76 (1.32%)	0/75 (0%)
Hypotony of eye [A] †	0/74 (0%)	0/76 (0%)	1/75 (1.33%)
Necrotising retinitis [A] †	1/74 (1.35%)	0/76 (0%)	0/75 (0%)
Pupillary disorder [A] †	1/74 (1.35%)	0/76 (0%)	0/75 (0%)
Retinal Detachment [A] †	0/74 (0%)	2/76 (2.63%)	2/75 (2.67%)
Uveitis [A] †	0/74 (0%)	1/76 (1.32%)	0/75 (0%)
Gastrointestinal disorders			
Small intestinal obstruction [A] †	1/74 (1.35%)	0/76 (0%)	0/75 (0%)
Infections and infestations			
Pelvic inflammatory disease [A] †	0/74 (0%)	1/76 (1.32%)	0/75 (0%)
Pyelonephritis [A] †	0/74 (0%)	0/76 (0%)	1/75 (1.33%)
Investigations			
HIV test positive [A] †	1/74 (1.35%)	0/76 (0%)	0/75 (0%)
Metabolism and nutrition disorders			
Ketoacidosis [A] †	1/74 (1.35%)	0/76 (0%)	0/75 (0%)
Musculoskeletal and connective tissue disorders			
Ankylosing spondylitis [A] †	0/74 (0%)	0/76 (0%)	1/75 (1.33%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Pancreatic Carcinoma [A] †	1/74 (1.35%)	0/76 (0%)	0/75 (0%)
Nervous system disorders			
Cerebellar infarction [A] †	0/74 (0%)	1/76 (1.32%)	0/75 (0%)
Cerebrovascular Accident [A] †	0/74 (0%)	1/76 (1.32%)	0/75 (0%)
Respiratory, thoracic and mediastinal disorders			

	Dexamethasone 350 µg	Dexamethasone 700 µg	Sham
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Pulmonary embolism [A] †	1/74 (1.35%)	0/76 (0%)	0/75 (0%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA (11.1)

Other Adverse Events

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

	Dexamethasone 350 µg	Dexamethasone 700 µg	Sham
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	58/74 (78.38%)	61/76 (80.26%)	51/75 (68%)
Eye disorders			
Cataract [A] †	6/74 (8.11%)	9/76 (11.84%)	7/75 (9.33%)
Cataract subcapsular [A] †	5/74 (6.76%)	2/76 (2.63%)	4/75 (5.33%)
Conjunctival haemorrhage [A] †	13/74 (17.57%)	23/76 (30.26%)	16/75 (21.33%)
Conjunctival hyperaemia [A] †	7/74 (9.46%)	5/76 (6.58%)	7/75 (9.33%)
Conjunctivitis [A] †	3/74 (4.05%)	1/76 (1.32%)	4/75 (5.33%)
Eye Pain [A] *	8/74 (10.81%)	11/76 (14.47%)	10/75 (13.33%)
Eye irritation [A] *	2/74 (2.7%)	4/76 (5.26%)	3/75 (4%)
Eye pruritis [A] *	3/74 (4.05%)	3/76 (3.95%)	5/75 (6.67%)
Eye swelling [A] *	1/74 (1.35%)	1/76 (1.32%)	4/75 (5.33%)
Intermediate uveitis [A] †	0/74 (0%)	4/76 (5.26%)	1/75 (1.33%)
Iridocyclitis [A] †	2/74 (2.7%)	11/76 (14.47%)	5/75 (6.67%)
Macular oedema [A] †	4/74 (5.41%)	3/76 (3.95%)	6/75 (8%)
Myodesopsia [A] †	5/74 (6.76%)	7/76 (9.21%)	5/75 (6.67%)
Ocular discomfort [A] *	3/74 (4.05%)	10/76 (13.16%)	6/75 (8%)
Ocular hypertension [A] †	7/74 (9.46%)	6/76 (7.89%)	0/75 (0%)

	Dexamethasone 350 µg	Dexamethasone 700 µg	Sham
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Uveitis [A] †	7/74 (9.46%)	10/76 (13.16%)	10/75 (13.33%)
Vision blurred [A] *	4/74 (5.41%)	5/76 (6.58%)	3/75 (4%)
Visual acuity reduced [A] †	7/74 (9.46%)	3/76 (3.95%)	6/75 (8%)
Gastrointestinal disorders			
Nausea [A] *	2/74 (2.7%)	0/76 (0%)	4/75 (5.33%)
Investigations			
Intraocular pressure increased [A] †	17/74 (22.97%)	19/76 (25%)	5/75 (6.67%)
Nervous system disorders			
Headache [A] *	6/74 (8.11%)	5/76 (6.58%)	5/75 (6.67%)

† Indicates events were collected by systematic assessment.
* Indicates events were collected by non-systematic methods.
A Term from vocabulary, MedDRA (11.1)

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:

Name/Official Title: Therapeutic Area Head
Organization: Allergan, Inc
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