

ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: May 27, 2011

ClinicalTrials.gov ID: NCT00333996

Study Identification

Unique Protocol ID: 206207-015

Brief Title: A Study of the Safety and Efficacy of a New Treatment for Non-Infectious Anterior Uveitis

Official Title:

Secondary IDs:

Study Status

Record Verification: May 2011

Overall Status: Terminated

Study Start: May 2006

Primary Completion: March 2007 [Actual]

Study Completion: March 2007 [Actual]

Sponsor/Collaborators

Sponsor: Allergan

Responsible Party:

Collaborators:

Oversight

FDA Regulated?: Yes

Applicable Trial?: Section 801 Clinical Trial? No
Delayed Posting?

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 IPD?:

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 anterior uveitis.

Detailed Description:

Conditions

Conditions: Anterior Uveitis

Keywords:

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 2/Phase 3

Intervention Model: Parallel Assignment

Number of Arms:

Masking: Double Blind

Allocation: Randomized

Endpoint Classification: Safety/Efficacy Study

Enrollment: 5 [Actual]

Arms and Interventions

Intervention Details:

Drug: Dexamethasone

Outcome Measures

Primary Outcome Measure:

1. Anterior Chamber Cell
[Time Frame:] [Safety Issue:]

Eligibility

Minimum Age: 18 Years

Maximum Age:

Gender: Both

Accepts Healthy Volunteers?: No

Criteria: Inclusion Criteria:

- 18 years or older with a diagnosis of non-infectious anterior uveitis in at least one eye

Exclusion Criteria:

- Uncontrolled systemic disease
- Any active ocular infections

Contacts/Locations

Study Officials: Allergan Inc.
Study Chair
Allergan

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

References

Citations:

Links:

Study Data/Documents: