Study Title:	A Real-world Study on the Efficacy and Safety of 9% Dexamethasone Insert in the Treatment of Postoperative Inflammation Following Cataract Surgery
Study Drug:	9% Dexamethasone Insert
Sponsor:	Ocumension Therapeutics (Shanghai) Co., Ltd 56F, One Museum Place, 669 Xin Zha Road, Jing'an District, Shanghai, PRC 200041
Study Indication:	Postoperative inflammation following cataract surgery
Protocol No.:	OT-502-002 NCT06497699 June 30, 2022

Study Summary

Title	A Real-world Study on the Efficacy and Safety of 9% Dexamethasone Insert in the Treatment of Postoperative Inflammation Following Cataract Surgery
Protocol Number	OT-502-002
Study Phase	Real-word Study
Study Duration	90 days
Study Center(s)	2 sites
Objectives	To evaluate the efficacy and safety of Dexamethasone Insert in the treatment of postoperative inflammation following cataract surgery in real-world clinical settings; and to evaluate the ease of use, time taken, and safety of the Dexamethasone Insert injector
Numbers of subjects	Plan: 263 subjects (113 subjects in the 9% Dexamethasone Insert group, 150 subjects in the external control group). Actual enrollment: 113 subjects in the 9% Dexamethasone Insert group, 150 subjects in the external control group; after propensity score (PS) 1:1 matching, 208 subjects (104 subjects in the 9% Dexamethasone Insert group, 104 subjects in the external control group) were included in the post-matching analysis.
Eligibility Criteria	Inclusion Criteria: 1) Patients must be able to understand and sign the informed consent form (ICF), and be able to comply with all study procedures. 2) Male or female patients over 40 years old who planned to undergo phacoemulsification combined with intraocular lens implantation surgery. Exclusion Criteria: 1) Known allergy to dexamethasone or any component of the Dexamethasone Insert. 2) History of endophthalmitis of any cause in either eye, presence of corneal abnormalities or malnutrition. 3) Patients with ocular hypertension, with an intraocular pressure (IOP) >21 mmHg in the study eye at screening, regardless of anti-glaucoma monotherapy. 4) Posterior capsule rupture or lens dislocation, anterior hyaloid membrane rupture, vitreous loss, and floppy iris syndrome during cataract surgery. 5) Other circumstances that, in the opinion of the investigator, the subject was not suitable for participation in the study

1.Introduction

Since the development of synthetic corticosteroids in the 1950s, corticosteroids have been used to treat eye disorders. They are important compounds for the treatment of inflammatory diseases. After entering cells, these compounds bind to glucocorticoid receptors, and are transported to the nucleus, activating the expression of anti-inflammatory genes, and inhibiting the expression of pro-inflammatory genes.

Dexamethasone was developed in the 1960s for the treatment of eye disorders and has since been used in ophthalmology. In current clinical practice, dexamethasone is used as a topical eye drop (in the form of a 1% ophthalmic suspension) to treat eye inflammation. Corticosteroid eye drops are commonly used to treat inflammation associated with cataract operations. Eye drops may need to be administered multiple times a day, presenting potential compliance issues; if compliance is poor, the expected therapeutic effect may not be achieved. As an alternative medication, dexamethasone delivered via short-term delivery systems can ensure subject compliance.

The Dexamethasone Insert, a new corticosteroid intraocular implant developed by EyePoint Pharmaceuticals in the United States (brand name DEXYCU®), was approved by the United States Food and Drug Administration (FDA) in February 2018 (approval number: NDA 208912) for the treatment of postoperative ocular inflammation. Under the support of the "National Nine Policies", drugs that have been approved for marketing in developed countries in Europe and America, not yet approved in China, and are urgently needed clinically, can be "piloted" in the Hainan Boao Lecheng International Medical Tourism Pilot Zone. In line with national spirit and the current urgent clinical needs domestically, the Hainan Provincial Health Commission and the Hainan Provincial Medical Products Administration have approved the use of the Dexamethasone Insert in the Hainan Boao Lecheng International Medical Tourism Pilot Zone.

The Ophthalmic Center of Boao Super Hospital relies on the advanced talents, technology, resources, and expert support of the Eye Hospital Affiliated to Wenzhou Medical University, covering all optometry disciplines, and shares resources with the Eye Hospital Affiliated to Wenzhou Medical University in clinical diagnosis, telemedicine, and joint discipline construction. Therefore, a real-world study on the efficacy and safety of the Dexamethasone Insert was conducted at the Ophthalmic Center of Boao Super Hospital, with research processes (including subject screening, Dexamethasone Insert operation, subject data generation, and postoperative follow-up) consistent with real-world clinical diagnosis and treatment standards, and the study results could be representative of real-world data.

2.Overall Study Design and Plan

This was a prospective, real-world study. It was planned to prospectively collect the medical histories and follow-up data of 113 subjects who received Dexamethasone Insert in real-world settings in China, to evaluate the efficacy and safety of Dexamethasone Insert, and conduct a survey among 30 injector users on the ease of use, time taken, and safety of using the Dexamethasone Insert injector. Prospectively enrolled subjects returned to the study sites in Hainan for follow-up on Days 1, 8, 30, and 90 after Dexamethasone Insert injection. In addition to prospectively collecting data from subjects receiving Dexamethasone Insert as mentioned above, data from 150 cataract subjects previously treated using conventional clinical methods at selected medical institutions were also prospectively collected as an external control (conventional treatment) to further evaluate the efficacy and safety of the Dexamethasone Insert. Prospective collection of data of the external control subjects was conducted as consistently as possible with that of the Dexamethasone Insert group.

3. Selection of Study Population

3.1 Inclusion Criteria

Only subjects who met all of the following conditions were included in this study:

1) Patients must be able to understand and sign the informed consent form (ICF), and be able to comply with all study procedures.

2) Male or female patients over 40 years old who planned to undergo phacoemulsification combined with intraocular lens implantation surgery.

3.2 Exclusion Criteria

Subjects were not allowed to participate in this study if they met any of the following criteria:

1) Known allergy to dexamethasone or any component of the Dexamethasone Insert.

2) History of endophthalmitis of any cause in either eye, presence of corneal abnormalities or malnutrition.

3) Patients with ocular hypertension, with an IOP >21 mmHg in the study eye at screening, regardless of anti-glaucoma monotherapy.

4) Posterior capsule rupture or lens dislocation, anterior hyaloid membrane rupture, vitreous loss, and floppy iris syndrome during cataract surgery.

5) Other circumstances that, in the opinion of the investigator, the subject was not suitable for participation in the study.

4. Statistical Plan

Descriptive statistics will be performed for de-identified demographic data, surgical details, clinical outcomes, and surgeon satisfaction.