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A clinical trial to assess the preliminary safety and treatment benefit of a long-acting anti-inflammatory medication for cataract surgery

Submission date
22/12/2020

Recruitment status
No longer recruiting

Registration date
23/12/2020

Overall study status
Completed

Last Edited
14/01/2022

Condition category
Eye Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
OcuRing-K™ is a long-acting implant that contains ketorolac, an anti-inflammatory medication used in eye drops to prevent inflammation and pain after cataract surgery. Eye drops are known to have side effects and can be burdensome for patients to self-administer. A pilot study is being conducted to assess the safety and potential treatment benefit of OcuRing-K™ as an alternative to eye drops for patients undergoing cataract surgery.

Who can participate?
Adults between the ages of 18 to 85 planning to undergo cataract surgery may be eligible to participate in this study.

What does the study involve?
Participation in study is no different from undergoing ordinary cataract surgery. The surgical procedure will be performed according to the standard of care, and the timing and duration of follow-up examinations will be the same as for ordinary cataract surgery.

What are the possible benefits and risks of participating?
Benefits to participating include not needing to take an anti-inflammatory eye drop after cataract surgery and contributing to the scientific research for the greater good of society. Risks associated with participation in the study include exposure to a new drug inside the eye, which may include inflammation, infection and elevation of eye pressure. These risks are not significantly different from the usual risks associated cataract surgery.

Where is the study run from?
Asociación para Evitar la Ceguera en México (Mexico)

When is the study starting and how long is it expected to run for?
From October 2019 to February 2020

Who is funding the study?
LayerBio, Inc (USA)

Who is the main contact?
Dr. Roberto Gonzalez-Salinas
dr.gonzalezsalinas@apec.com.mx

Contact information

Type(s)
Scientific

Contact name
Dr Roberto Gonzalez-Salinas

ORCID ID
http://orcid.org/0000-0001-6654-5191

Contact details
Asociación para Evitar la Ceguera en México
Vicente García Torres 46
San Lucas Coyoacán
Mexico City
Mexico
04030
+52 55 1084 1400
dr.gonzalezsalinas@apec.com.mx

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
OCUR-1

Study information

Scientific Title
Pilot study to assess safety and efficacy of OcuRing-K™ ketorolac implant for cataract surgery

Study objectives
OcuRing-K™ is safe and well tolerated by subjects undergoing cataract surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/12/2019, Comité de Ética en lnvestigación, (Asociación para Evitar la Ceguera en México, Vicente García Torres 46, San Lucas Coyoacán, PO. 04030. Mexico City, Mexico; no telephone contact available; no email contact available)

Study design
Single-site interventional single-arm open-label non-randomized trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Treatment of inflammation and pain associated with cataract surgery

Interventions
Participants in this study will undergo cataract surgery according to the standard of care. A single dose of the study drug will be administered into the eye at the time of surgery. Follow up visits will occur at 1, 7 and 28 days after cataract surgery. The content and duration of each postoperative visit is the same as the standard of care. No additional time is required for participation in this study.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
Phenylephrine, ketorolac, OcuRing-K™ ketorolac ophthalmic implant

Primary outcome measure
1. Safety as measured by the frequency and severity of treatment-related adverse events assessed from baseline to 28 days

Secondary outcome measures

1. Pain measured by visual analog scale (VAS) at baseline, 1, 7, and 28 days
2. Ocular inflammation measured by anterior chamber cell (ACC) at baseline, 1, 7, and 28 days

Overall study start date
21/10/2019

Completion date
06/02/2020

Eligibility

Key inclusion criteria
1. Undergoing unilateral cataract extraction and implantation of a monofocal intraocular lens implantation (IOL)
2. Aged ≥18 and ≤ 85 years
3. Willing and able to comply with the protocol requirements, has gone through the consent process, and has signed an approved informed consent form

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
5

Total final enrolment
5

Key exclusion criteria
1. Severe/serious corneal pathology which may preclude study completion.
2. Any extraocular/intraocular inflammation in the study eye at screening visit (blepharitis allowed if mild only, and no concurrent conjunctivitis or lid erythema/edema) or ongoing, unresolved uveitis
3. Ocular surgery of any kind in the study eye within 6 months prior to baseline visit
4. Scheduled for surgery in the fellow eye within the study period
5. Any medical condition or clinical laboratory test which in the judgment of the Investigator makes the subject unsuitable for the study
6. Anterior chamber inflammation as measured by slit lamp examination at baseline
7. Use of any topical ocular medication in either eye, other than tear substitute for dry eye, at least 2 weeks prior to the baseline visit
8. Currently or within the past 5 years, have a history of malignancy other than successfully treated squamous or basal cell carcinoma of the skin or successfully treated in situ cervical

cancer
9. Oral corticosteroid within the past 14 days prior to Visit 1 or topical corticosteroid ≤ 48 h prior to Visit 1
10. Prescribed nonsteroidal anti-inflammatory drugs (NSAIDs) or immunosuppressive agents, unless the dose has been stable for the last six weeks and no change in dosing is anticipated for the duration of the study
11. Intravitreal or sub-Tenon corticosteroid treatment in the study eye within the past 6 months prior to Visit 1
12. Intracocular pressure (IOP) ≥ 25 mmHg at baseline, a history of glaucoma, or require ocular antihypertensive medications in the study eye
13. Known steroid intraocular pressure responders in either eye
14. Have participated in another investigational device or drug study within 3 months prior to Visit 1

Date of first enrolment
03/12/2019

Date of final enrolment
07/01/2020

Locations

Countries of recruitment
Mexico

Study participating centre
Asociación para Evitar la Ceguera en México
Vicente García Torres 46
San Lucas Coyoacán
Mexico City
Mexico
04030

Sponsor information

Organisation
Layerbio, Inc.

Sponsor details
60 Cary Ave
Lexington
United States of America
02421
+1 (617) 453-8210
ken@layerbio.com

Sponsor type
Industry

Website
https://www.layerbio.com

Funder(s)

Funder type
Industry

Funder Name
LayerBio, Inc.

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/06/2021

Individual participant data (IPD) sharing plan
Participant-level data will be included in the peer-reviewed publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results	Presented at ARVO	01/06/2021	14/01/2022	No	No