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The effect of 0.05% Cyclosporine A eyedrops in patients after cataract surgery

Submission date	Recruitment status	[_] Prospectively registered
28/03/2020	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
06/04/2020	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
12/01/2021	Eye Diseases	

Plain English summary of protocol

Background and study aims
Cataracts are when the lens of your eye, a small transparent disc, develops cloudy patches. Cataract surgery involves replacing the cloudy lens inside the eye with an artificial one.
The Meibomian glands along the rims of the eyelid produce meibum, an oily substance that prevents evaporation of the eye's tear film. Meibomian gland dysfunction (MGD) often occurs after cataract surgery.
Cyclosporine A (CsA) eye drops are a new treatment for MGD and dry eye syndrome after cataract surgery. The usual treatment is with Carboxymethyl cellulose (CMC) eye drops.

Who can participate?
Adult cataract patients with normal lid position and closure and not suffering from any ocular diseases.

What does the study involve?
Participants will be randomly allocated to receive 0.05% CsA or 0.5% Carboxymethyl cellulose (CMC) over three months following cataract surgery. Subjective and objective assessments are performed in each preoperative and postoperative visit.

What are the possible benefits and risks of participating?
When participating in the study, there might be no risks or benefits for patients. This is a controlled study comparing the group with and without the use of specific eye drops that are commercially available and have clinical safety. There is no direct benefit when the patient participates in the study.

Where is the study run from?
Department of Ophthalmology, Pusan National University School of Medicine, Yangsan (South Korea)

When is the study starting and how long is it expected to run for?
April 2019 to November 2019

Who is funding the study?
Pusan National University Yangsan Hospital (South Korea)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Efficacy of 0.05% Cyclosporine A on the lipid layer and meibomian gland after cataract surgery: a randomized, double-masked study

Study objectives
0.05% cyclospoine A might improve MGD dysfunction and dry eye syndrome by comparison to 0.5% carboxymethyl cellulose after cataract surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 04/04/2019, Pusan National University Yangsan Hospital Institutional Review Board (#20 Geumo-ro, Mulgeum-eup, Yangsan 50612, South Korea; +82-55-360-3854; pnuyhirb@gmail.com), ref: 05-2019-049

Study design
Prospective randomized double-masked comparative clinical trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Dry eye syndrome, meibomian gland dysfunction

Interventions
Eligible patients are randomized using the random number method into two treatment groups. The first group will use 0.05% CsA ophthalmic emulsion (Restasis®, Allergan Inc., Irvine, CA) twice daily over three months following cataract surgery. The second group receive standard postoperative treatment with 0.5% carboxymethyl cellulose (CMC) (Refresh plus®, Allergan Inc., Irvine, CA).

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
0.05% CsA ophthalmic emulsion (Restasis®, Allergan Inc., Irvine, CA); 0.5% carboxymethyl cellulose (CMC) (Refresh plus®, Allergan Inc., Irvine, CA)

Primary outcome measure
At baseline and three months.
1. Ocular surface status parameters:

1.1. Lipid layer thickness (LLT) using an interferometer
1.2. Schirmer’s type I test
1.3. Tear breakup time (TBUT)
2. Ocular Surface Disease Index (OSDI) questionnaire to evaluate the patients’ symptoms
3. Meiboscores with the LipiView® interferometer to calculate the degree of meibomian gland dysfunction

Secondary outcome measures
none

Overall study start date
01/01/2018

Completion date
30/11/2019

Eligibility

Key inclusion criteria
Adult cataract patients with normal lid position and closure and not suffering from any ocular diseases

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
50 patients

Total final enrolment
50

Key exclusion criteria
1. Patients who had used topical anti-inflammatory, antibiotic, or other medication during the previous 90 days before surgery
2. Eyes with a history of trauma, ocular surgery, laser or systemic treatment known to affect tear secretion, autoimmune disease, current use of contact lenses, and/or history of slit-lamp evidence of eye surface disorders

Date of first enrolment
04/04/2019

Date of final enrolment
31/05/2019

Locations

Countries of recruitment
Korea, South

Study participating centre
Pusan National University School of Medicine
Department of Ophthalmology
20-Geumo-ro
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Sponsor information

Organisation
Pusan National University Yangsan Hospital

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Sponsor type
Hospital/treatment centre

Website
http://www.pnuyh.or.kr/pnuh/main/main.do?rbsIdx=1

ROR
https://ror.org/04kgg1090

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Pusan National University Yangsan Hospital

Results and Publications

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

Intention to publish date
20/04/2020

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			15/05/2020	No	No
Results article	results	11/01/2021	12/01/2021	Yes	No