

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

<b>Submission date</b> 28/03/2020	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 06/04/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 12/01/2021	<b>Condition category</b> Eye Diseases	<input type="checkbox"/> Individual participant data

## 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?  
Dr Min Seung Min Seung, kangminseung91@gmail.com

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Min Seung Kang

**ORCID ID**  
<https://orcid.org/0000-0001-5026-4117>

**Contact details**  
Pusan National University School of Medicine  
20-Geumo-ro  
Mulgeum-eup  
Yangsan  
Korea, South  
50612  
+82 55-360-1447  
kangminseung91@gmail.com

## 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

Mulgeum-eup

Yang San

Korea, South

50612

# Sponsor information

## Organisation

Pusan National University Yangsan Hospital

## Sponsor details

20-Geumo-ro

Mulgeum-eup

Yangsan

Korea, South

50612

+82 55-360-1447

jiel75@hanmail.net

## Sponsor type

Hospital/treatment centre

## Website

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

## ROR

<https://ror.org/04kkg1090>

# 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?
<a href="#">Protocol file</a>			15/05/2020	No	No
<a href="#">Results article</a>	results	11/01/2021	12/01/2021	Yes	No