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Comparing sodium hyaluronate effects on eye moisture after cataract surgery

Submission date 10/08/2023	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 25/08/2023	**Overall study status** Completed	
Last Edited 31/07/2024	**Condition category** 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. Postoperative Dry Eye Syndrome (DES) often occurs after cataract surgery. Sodium hyaluronate eye solution is a common treatment for dry eye syndrome after cataract surgery. The aim of this study is to compare the efficacy of 0.15% sodium hyaluronate eye drops in MGD dysfunction and dry eye syndrome after cataract surgery in comparison with 0.1% sodium hyaluronate eye drops.

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

What does the study involve?
Participants will be randomly allocated to use 0.15% or 0.1% sodium hyaluronate eye drops for 6 weeks following cataract surgery. Eye assessments are performed at each visit 1week before and 1, 3, 6 weeks after surgery.

What are the possible benefits and risks of participating?
There may be no risks or benefits for the participants. The eye drops are commercially available and have proven clinical safety.

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

When is the study starting and how long is it expected to run for?
February 2022 to December 2023

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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Study information

Scientific Title
Efficacy of 0.15% sodium hyaluronate on tear breakup time (TBUT), Schirmer's I test score, ocular surface disease index (OSDI) score, corneal staining score (CSS), lipid layer thickness (LLT) and meiboscore after cataract surgery: a randomized, double-masked study

Study objectives
0.15% sodium hyaluronate might improve ocular surface status and dry eye syndrome in comparison with 0.1% sodium hyaluronate after cataract surgery.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 06/05/2022, Pusan National University Yangsan Hospital Institutional Review Board (#20 Geumo-ro, Mulgeum-eup, Yangsan, 50612, Korea, South; +84 55 360 3854; pnyhirb@gmail.com), ref: 05-2022-084

Primary study design
Interventional

Study design
Prospective randomized double-masked comparative clinical trial

Study type(s)
Treatment

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

Interventions
Patients are randomized using the random number method into two treatment groups.
The first group will use 0.15% sodium hyaluronate ophthalmic solution (Hyalu Mini®, Hanmi P harma Inc., Seoul, Korea) 4 times daily over 6 weeks following cataract surgery.
The second group receive standard postoperative treatment with 0.1% sodium hyaluronate (HyalQ, Ildong Pharmaceutical Inc., Seoul, Korea)
Eye assessments are performed at each visit 1 week before and 1, 3, 6 weeks after surgery.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
0.15% sodium hyaluronate ophthalmic solution (Hyalu Mini®, Hanmi P harma Inc., Seoul, Korea)
0.1% sodium hyaluronate (HyalQ, Ildong Pharmaceutical Inc., Seoul, Korea)

Primary outcome(s)
Measured at baseline (1 week before cataract surgery) and 1, 3, 6 weeks after cataract surgery:
1. Ocular surface status parameters:
1.1. Lipid layer thickness (LLT) measured using an interferometer
1.2. Schirmer’s type I test using COLOR BAR by Eagle Vision Inc.
1.3. Tear breakup time (TBUT), corneal staining score(CSS), meiboscore were measured by an ophthalmologist
2. Patients’ symptoms measured using Ocular Surface Disease Index (OSDI) questionnaire

Key secondary outcome(s)
There are no secondary outcome measures

Completion date
31/12/2023

Eligibility

Key inclusion criteria
1. Be male or female, aged 19 years to 90 years
2. Have a tear breakup time (TBUT) of 10 seconds or more
3. Have a Schirmer’s I test result of 10 mm or more
4. Have not used diquafosol-based eye drops, artificial tear drops, steroid eye drops, or antibiotic eye drops within 3 months before participation

5. Show normal blinking during a slit lamp exam
6. Voluntarily agree to participate in this study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
19 Years

Upper age limit
90 Years

Sex
All

Total final enrolment
70

Key exclusion criteria
1. Has Sjögren's syndrome
2. Has severe blepharitis
3. Had ocular surgery or laser eye surgery
4. Has severe ocular inflammation/infection
5. Is using eye drop treatment for dry eyes, such as glaucoma or allergies
6. Shows sensitivity to the study drugs
7. Is considered to be ineligible for participation owing to reasons other than the aforementioned exclusion criteria based on the judgment of the principal researcher

Date of first enrolment
11/05/2022

Date of final enrolment
30/11/2022

Locations

Countries of recruitment
Korea, South

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

Mulgeum-eup
Yangsan
Korea, South
50612

Sponsor information

Organisation
Pusan National University Yangsan Hospital

ROR
https://ror.org/04kgg1090

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Pusan National University Yangsan Hospital

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made 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?
Results article		30/07/2024	31/07/2024	Yes	No