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The effect of 3% diquafosol sodium eye drops in patients after cataract surgery

Submission date
04/10/2020

Recruitment status
No longer recruiting

Registration date
13/11/2020

Overall study status
Completed

Last Edited
29/04/2021

Condition category
Eye Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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. Postoperative Dry Eye Syndrome (DES) often occurs after cataract surgery. Diquafosol sodium eye solution is a new treatment for dry eye syndrome after cataract surgery. One of the usual treatments for post-cataract surgery is sodium hyaluronate eye drops. The aim of this study is to find out whether diquafosol sodium eye drops improve MGD dysfunction and dry eye syndrome after cataract surgery in comparison with 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 diquafosol sodium or sodium hyaluronate eye drops for 15 weeks following cataract surgery. Eye assessments are performed at each visit 1week before and 3, 7, 15 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?
January 2020 to November 2020

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

Who is the main contact?
Dr Sangyoon Kim
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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 3% diquafosol sodium on tear breakup time (TBUT), Schirmer’s I test score, ocular surface disease index (OSDI) score, lipid layer thickness (LLT) after cataract surgery: a randomized, double-masked study

Study objectives
Current study hypothesis as of 28/01/2021:
3% diquafosol sodium might improve ocular surface status and dry eye syndrome in comparison with 0.1% sodium hyaluronate after cataract surgery.

Previous study hypothesis:
3% diquafosol sodium might improve meibomian gland (MGD) dysfunction and dry eye syndrome in comparison with 0.1% sodium hyaluronate after cataract surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/01/2020, Pusan National University Yangsan Hospital Institutional Review Board (#20 Geumo-ro, Mulgeum-eup, Yangsan 50612, South Korea; +82 (0)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 to request a participant information sheet

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

Interventions
Current interventions as of 28/01/2021:
Eligible patients are randomized using the random number method into two treatment groups. The first group will use 3% diquafosol sodium ophthalmic solution (Diquas-s®, Mitsubishi Tanabe Pharma Inc., Osaka, Japan) six times daily over 15 weeks following cataract surgery. The second group receive standard postoperative treatment with 0.1% sodium hyaluronate (HyalQ, Ildong Pharmaceutical Inc., Seoul, Korea).

Previous interventions:
Eligible patients are randomized using the random number method into two treatment groups. The first group will use 3% diquafosol sodium ophthalmic solution (Diquas-s®, Mitsubishi Tanabe Pharma Inc., Osaka, Japan) six times daily over 4 months following cataract surgery. The second group receive standard postoperative treatment with 0.1% sodium hyaluronate (HyalQ, Ildong Pharmaceutical Inc., Seoul, Korea).

Intervention Type

Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
3% diquas sodium ophthalmic solution(Diquas-s®, Mitsubishi Tanabe Pharma Inc., Osaka, Japan); 0.1% sodium hyaluronate (HyalQ, Ildong Pharmaceutical Inc., Seoul, Korea)

Primary outcome measure
Current primary outcome measure as of 28/01/2021:
Measured at baseline (1 week before cataract surgery) and 3, 7, 15 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) measured by an ophthalmologist
2. Patients' symptoms measured using Ocular Surface Disease Index (OSDI) questionnaire

Previous primary outcome measure:
Measured at baseline and 4 months:
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) measured by an ophthalmologist
2. Patients' symptoms measured using Ocular Surface Disease Index (OSDI) questionnaire
3. Meibomian gland dysfunction assessed using Meiboscores with the LipiView® interferometer

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/01/2020

Completion date
09/11/2020

Eligibility

Key inclusion criteria
Current inclusion criteria as of 28/01/2021:
In order to be eligible for participation in this study, the subject had to:
1. Be male or female, aged 19 years or older
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

Previous 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
100

Total final enrolment
60

Key exclusion criteria
Current exclusion criteria as of 28/01/2021:
The subject is excluded from the study if the subject either:
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

Previous 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
20/02/2020

Date of final enrolment
18/07/2020

Locations

Countries of recruitment
Korea, South

Study participating centre
Pusan National University School of Medicine
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Sponsor information

Organisation
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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
20/04/2021

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		27/04/2021	29/04/2021	Yes	No