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The efficacy of diquafosol eyedrops in dry eye syndrome

Submission date
03/05/2014

Recruitment status
No longer recruiting

Registration date
27/05/2014

Overall study status
Completed

Last Edited
27/05/2014

Condition category
Eye Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Dry eye disease occurs when the eyes do not make enough tears or the tears evaporate too quickly, leading to the eyes drying out and becoming inflamed (red and swollen) and irritated. Our goal is to compare the effectiveness of preservative-free sodium hyaluronate and diquafosol combination treatment, treatment with diquafosol alone and preserved sodium hyaluronate alone in treating dry eye disease.

Who can participate?
Patients aged over 21 with dry eye disease can take part in this study.

What does the study involve?,
Patients were randomly allocated to one of three groups: Group 1 (50 patients) was treated with preserved sodium hyaluronate , Group 2 (50 patients) with diquafosol, and Group 3 (50 patients) with diquafosol and preservative-free sodium hyaluronate eyedrops for 3 months. We will perform various tests and laboratory measurements at the start of the study and 1, 2, and 3 months after the treatment.

What are the possible benefits and risks of participating?
Treatment of dry eye syndrome will relieve dry eye symptoms. There are no risks involved in this study.

Where is the study run from?
Bucheon St. Mary's Hospital (South Korea).

When is the study starting and how long is it expected to run for?
Recruitment started in early 2013. Participants were enrolled on the study for a period of 6 months between May 2013 and December 2013.

Who is funding the study?
National Research Foundation of Korea (NRF) (South Korea).

Who is the main contact?
Professor Eun Chul Kim
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Contact information

Type(s)
Scientific

Contact name
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420-717

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Additive effect of preservative-free sodium hyaluronate 0.1% in treatment of dry eye syndrome with diquafosol 3% eyedrops

Study objectives
Preservative-free lubricants can augment the treatment effect of diquafosol by enhancing ocular surface stabilization.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional review board regulations (IRB) of Bucheon St Mary's Hospital

Study design
Prospective randomized controlled parallel-group study, 14/02/2011, NO: HC11RIM10003

Primary study design
Interventional

Secondary study design
Randomised controlled 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

Interventions
Participants were randomized to one of the following three groups:
Group 1 (50 patients, 50 eyes) were treated with preserved sodium hyaluronate 0.1% eyedrops (Lacure, Samil, Seoul, Korea) (four times a day) in the 1, 2 and 3 months
Group 2 (50 patients, 50 eyes) were treated with diquafosol 3% eyedrops (four times a day) in the 1, 2 and 3 months
Group 3 (50 patients ,50 eyes) were treated with diquafosol 3% and preservative-free sodium hyaluronate 0.1% eyedrops (Tearin free, DHP Korea, Seoul, Korea) (four times a day) in the 1, 2 and 3 months

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Ocular surface disease index (OSDI) scoring
2. tBUT
3. Schirmer I test (without anesthesia)

All outcomes were measured before treatment and at 1, 2 and 3 months after the start of treatment.

Secondary outcome measures
1. Corneal fluorescein staining
2. Conjunctival impression cytology

All outcomes were measured before treatment and at 1, 2 and 3 months after the start of treatment.

Overall study start date
01/05/2013

Completion date
01/12/2013

Eligibility

Key inclusion criteria
1. Low tear film break-up time (tBUT) (<5 seconds)
2. Low Schirmer I score (10 mm/5 minutes without anesthesia)
3. Mild corneal punctate fluorescein staining (staining score of ≥1) in either eye (scale 0 ~ 3)
4. At least 21 years old

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
150 patients

Key exclusion criteria
1. History of ocular injury, infection, non-dry eye ocular inflammation, trauma, or surgery within the prior 6 months
2. Presence of uncontrolled systemic disease

Date of first enrolment
01/05/2013

Date of final enrolment
01/12/2013

Locations

Countries of recruitment
Korea, South

Study participating centre

Department of Ophthalmology
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Sponsor information

Organisation
Bucheon St Mary's Hospital (South Korea)

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.cmcbucheon.or.kr/

ROR
https://ror.org/01fpnj063

Funder(s)

Funder type
Research organisation

Funder Name
National Research Foundation of Korea (NRF) (South Korea)

Alternative Name(s)
, National Research Foundation (South Korea), NRF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Korea, South

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration