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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**
Prof Eun Chul Kim

**Contact details**
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# Additional identifiers

# 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

**Primary study design**
Interventional

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

**Study type(s)**
Treatment

### 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(s)
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.

### Key secondary outcome(s)
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.

### 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

### Healthy volunteers allowed
No

**Age group**
Adult

**Sex**
All

**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**
Bucheon
Korea, South
420-717

# Sponsor information

**Organisation**
Bucheon St Mary's Hospital (South Korea)

**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

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not provided at time of registration