ISRCTN13765551 https://doi.org/10.1186/ISRCTN13765551

Comparison of the treatment effect of preservative-free vs preserved eye drops in patients with dry eye syndrome

Submission date 20/01/2014	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 05/02/2014	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 17/02/2014	**Condition category** Eye Diseases	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Studies show that preservatives in eye drop can trigger an inflammatory response. To the best of our knowledge, there is no report comparing the effects of preservative-free and preserved eye drops in dry eye syndrome. This study compares the antioxidants and inflammatory responses in tears of patients with dry eye syndrome treated with preservative-free eye drops versus eye drops with preservatives.

Who can participate?
21 years of age and over and diagnosed with dry eye syndrome.

What does the study involve
Participants were randomly allocated to receive either preservative-free eye drops or eye drops with preservatives. Various assessments will be carried out at the start of the study and at 1, 2 and 3 months after treatment.

What are the possible benefits and risks of participating?
Both preservative-free and preserved eye drops treatments may lead to significant improvement in symptoms of dry eye. There is no risk to participants.

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?
The study started in September 2012 and ran until December 2013.

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

Who is the main contact?.
Professor Eun Chul Kim

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Comparison of antioxidant and inflammatory cytokine activities in tears of patients with dry eye syndrome treated with preservative-free vs preserved eye drops

Study objectives
Dry eye syndrome is recognized as a highly prevalent inflammatory disease of the lacrimal functional unit caused by multifactorial reasons. Increase of the oxidative stress status in the conjunctiva of Sjogren syndrome patients appears to have a role in the pathogenesis of dry eye disease. Preservatives in eye drops can induce oxidative stress and inflammatory response in conjunctival epithelial cells and the rabbit dry eye model.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board at the Bucheon St. Mary's Hospital, 21/08/2013

Study design
Randomized comparative clinical trial

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
Permuted blocks were obtained using a computer-based random code generator (Research Randomizer; http://randomizer.org/).

50 patients (Group 1) were treated four times with preservative-free 0.1% sodium hyaluronate and 0.1% fluorometholone for the first month and preservative-free 0.1% sodium hyaluronate and 0.05% cyclosporine for the second and third month.

50 patients (Group 2) were treated four times with preserved 0.1% sodium hyaluronate and preserved 0.1% fluorometholone for the first month and preserved 0.1% sodium hyaluronate and 0.05% cyclosporine for the second and third month.

Following instillation of the eye drops, symptoms and signs of dry eye are measured.

Total duration of treatment and follow-up for each study arm: 3 months

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Ocular surface disease index (OSDI)
2. Corneal fluorescein staining
3. Schirmer tear test (without anesthesia)
4. Tear film break-up time (tBUT)
5. Symptom score of dry eye
6. Impression cytology

Measured at baseline, 1, 2 and 3 months.

Secondary outcome measures
Antioxidant and Inflammatory cytokine activities in tears measured by ELISA at baseline, 1, 2 and 3 months.

Overall study start date
01/09/2012

Completion date
01/12/2013

Eligibility

Key inclusion criteria
Eligible patients were at least 21 years of age and had a diagnosis of dry eye syndrome refractory to conventional management. Inclusion criteria were:
1. Schirmer test (without anesthesia) of 5 mm/5 minutes in at least one eye
2. Low tear film break-up time (tBUT) (<5 seconds)
3. Mild superficial punctate keratitis, defined as a corneal punctate fluorescein staining score of ≥1 in either eye (scale 0 [none] to 3 [severe]); and one or more moderate (≥2) dry eye related symptoms, including itching, burning, blurred vision, foreign body sensation, dryness, photophobia, soreness, or pain.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Group 1 (50 patients) was treated with preservative-free eye drops and group 2 (50 patients) was treated with preserved eye drops.

Key exclusion criteria
Patients were excluded if they had:
1. A history of any ocular disorder including injury, infection, non-dry-eye ocular inflammation, trauma, or surgery within the prior 6 months
2. Were receiving concurrent treatment that could interfere with interpretation of the study results
3. Had any uncontrolled systemic disease or significant illness; or were pregnant, lactating, or considering becoming pregnant.
4. Patients could be discontinued before the completion of the study because of adverse events, pregnancy, protocol violations, lack of efficacy, or administrative or personal reasons.

Date of first enrolment
01/09/2012

Date of final enrolment

01/12/2013

Locations

Countries of recruitment
Korea, South

Study participating centre
Bucheon St. Mary's Hospital
Bucheon
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Sponsor information

Organisation
Bucheon St. Mary's Hospital (Korea, South)

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01fpnj063

Funder(s)

Funder type
Government

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