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Clinical effect of anti-oxidant glasses in dry eye

Submission date 13/06/2015	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 23/06/2015	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 10/07/2023	**Condition category** Eye Diseases	[X] Individual participant data

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 aim is to study the clinical effectiveness and safety of wearable anti-oxidant glasses containing extracts of medicinal plants in patients with mild dry eye disease.

Who can participate?
Patients with mild dry eye.

What does the study involve?
Participants were randomly allocated to wear either glasses containing extracts of anti-oxidant medicinal plants or normal glasses. The glasses were applied for 15 minutes, three times a day. The participants' symptoms were evaluated at the start of the study and 4 and 8 weeks after treatment.

What are the possible benefits and risks of participating?
The participants' symptoms could improve. There is a risk of unknown side effects wearing anti-oxidant containing glasses.

Where is the study run from?
1. Department of Ophthalmology, Chonnam National University Medical School and Hospital (South Korea)
2. Department of Ophthalmology, Chung-Ang University Hospital, Chung-Ang University College of Medicine (South Korea).

When is the study starting and how long is it expected to run for?
From September 2012 to March 2013.

Who is funding the study?
1. BM Biotechnology Co., Ltd. (South Korea)
2. Chonnam National University Hospital Biomedical Research Institute (Korea)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
OP00082

Study information

Scientific Title
Clinical effect of anti-oxidant glasses containing extracts of medicinal plants in patients with dry eye disease: a multi-center, prospective, randomized, double-blind, placebo-controlled trial

Study objectives
Local delivery of anti-oxidant agents using glasses might be effective in controlling oxidative damages in dry eye disease.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board of the Chonnam National University Hospital, Chung-Ang University Hospital and the Korean Food and Drug Administration (No. MDCTC_2011_BM)

Study design
Prospective multicenter double-blind randomized placebo-controlled clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Dry eye is a disorder of the tear film due to tear deficiency or excessive evaporation, which causes damage to the interpalpebral ocular surface and is associated with symptoms of ocular discomfort

Interventions
Patients were randomly assigned to either the treatment or the placebo group. Participants inthe treatment group received commercially available glasses (EPA II-alpha, BM Biotechnology, Sunchon, South Korea) with a pad containing four anti-oxidant medicinal plant extracts including Schizonepeta tenuifolia var. japonica Kitagawa, Angelica dahurica Bentham ET hooker, Rehmannia glutinosa Liboschitz var. purpurea Makino, and Cassia tora L. Each treatment session was 15 minutes long and both groups underwent a treatment session three times a day for 8 weeks.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
-

Primary outcome measure
Change in subjective symptoms of dry eye disease. The subjective symptoms were graded using ocular surface disease index (OSDI) score (0 to 100), with higher scores representing greater disability. The patients answered the 12 items on the OSDI questionnaire that were graded on a scale of 0 to 4 (0: none of the time, 1: some of the time, 2: half of the time, 3: most of the time, 4: all of the time). The OSDI was calculated by ([sum of scores for all questions answered]×100)/

([total number of questions answered]×5). The OSDI score was evaluated at baseline, 4 weeks, and 8 weeks after treatment.

Secondary outcome measures
1. Tear film break up time - the time before the defect of fluorescein dye appeared in the stained tear film was measured and recorded (measured TBUT 3 times and averaged)
2. Schirmer's test (with anesthesia)
Both evaluated at baseline, 4 weeks, and 8 weeks after treatment.

Overall study start date
17/08/2012

Completion date
31/05/2013

Eligibility

Key inclusion criteria
1. One or more dry eye-related ocular symptoms (> 3 months) such as dryness, irritation and burning sensations
2. Ocular Surface Disease Index score from 13 to 32 (mild to moderate)
3. Tear film break-up time (BUT) of <10 s or a Schirmer's test (with application of a local anaesthetic) value <10 mm for 5 minutes

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
50

Key exclusion criteria
1. Pregnant women
2. Active eye and periocular skin inflammation
3. Vitamin A deficiency
4. Previous ocular surgery within 3 months
5. History of diabetic retinopathy, age-related macular degeneration, glaucoma
6. History of wearing contact lenses
7. History of active treatment for dry eyes such as punctal occlusion or the usage of anti-inflammatory eye drops (topical steroid or topical cyclosporin) within 1 month
8. Systemic condition or medication that could cause dry eye

Date of first enrolment
28/09/2012

Date of final enrolment
28/03/2013

Locations

Countries of recruitment
Korea, South

Study participating centre
Chonnam National University Medical School and Hospital
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Chung-Ang University Hospital
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Sponsor information

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Sponsor type
University/education

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Sponsor type
University/education

Funder(s)

Funder type
Industry

Funder Name
BM Biotechnology Co., Ltd.

Funder Name
Chonnam National University Hospital Biomedical Research Institute

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	12/10/2015		Yes	No
Dataset		12/10/2015	10/07/2023	No	No
Protocol (other)		12/10/2015	10/07/2023	No	No