

Clinical effect of anti-oxidant pads in patients with dry eye

Submission date 10/12/2015	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 14/12/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 17/08/2020	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Dry eye disease (or dry eye syndrome) is a common eye condition in which the eyes do not make enough tears or the tears evaporate too quickly. This causes the eyes to dry out, resulting in them becoming irritated, red and swollen. Sufferers may find that their eyelids have become stuck together overnight when they wake up. They may also experience blurred vision that improves after blinking. The aim of this study is to test anti-oxidant pads containing the plant extracts of *Chamaecyparis obtusa* and *Camellia japonica* to see whether they can help control the condition and alleviate symptoms.

Who can participate?

Adult patients with dry eye.

What does the study involve?

Patients are randomly allocated to either the treatment or the placebo (control) group. All participants are given glasses that are designed to wrap around the eye and hold eye pads in place. Participants in the treatment group are given eye pads that contain extracts of *Chamaecyparis obtusa* and *Camellia japonica*. Participants in the placebo group are also given eye pads but these do not contain the plant extracts. All participants wear the glasses while asleep for 4 weeks.

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 pads.

Where is the study run from?

Department of Ophthalmology, Chonnam National University Medical School and Hospital (South Korea)

When is the study starting and how long is it expected to run for?

November 2015 to December 2016.

Who is funding the study?
Forest Science and Technology Projects provided by the Korea Forest Service

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
OP00169

Study information

Scientific Title
Clinical effect of anti-oxidant pads containing extracts of *Chamaecyparis obtusa* and *Camellia japonica* in patients with dry eye disease.

Study objectives
Local delivery of anti-oxidant agents using pads 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, 26/11/2015, ref: CNUH-2015-232

Study design

Prospective double-blind randomized placebo-controlled clinical trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Dry eye

Interventions

Patients were randomly assigned to either the treatment or the placebo group.

All participants are given glasses composed of an external supporting cover that can be easily attached and detached from the face. The external supporting part of the glasses has been designed to wrap around the eye.

Participants in the treatment group are given eye pads to be inserted into the glasses that contain extracts of *Chamaecyparis obtusa* and *Camellia japonica*.

Participants in the placebo group are also given eye pads but these do not contain the plant extracts.

All participants wear the glasses while asleep for 4 weeks.

Intervention Type

Device

Primary outcome(s)

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 $([\text{sum of scores for all questions answered}] \times 100) / ([\text{total number of questions answered}] \times 5)$.

The OSDI score was evaluated at baseline, 4 weeks, and 8 weeks after treatment.

Key secondary outcome(s)

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.

Completion date

14/12/2016

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

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

14/12/2015

Date of final enrolment

14/01/2016

Locations**Countries of recruitment**

Korea, South

Study participating centre

Chonnam National University Medical School and Hospital
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Sponsor information

Organisation

Korea Forest Service

ROR

<https://ror.org/05bjbww34>

Funder(s)

Funder type

Government

Funder Name

Korea Forest Service

Alternative Name(s)

KFS

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Korea, South

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
	results				

[Results article](#)

01/01/2017

17/08/2020

Yes

No