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

Submission date	Recruitment status	[X] Prospectively registered
10/12/2015	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
14/12/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
17/08/2020	Eye Diseases	

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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 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
14/11/2015

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

Age group
Adult

Sex
Both

Target number of participants
50

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
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Sponsor type
Government

Website
http://www.forest.go.kr/newkfsweb/kfs/idx/Index.do?mn=KFS_01

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

Publication and dissemination plan
After completing this study, we would like to publish on SCI journal as soon as possible. Our study will demonstrate clinical effect of Chamaecyparis obtusa and Camellia japonicaor on dry eye disease.

Intention to publish date

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 article	results	01/01/2017	17/08/2020	Yes	No