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# Comparison of vitamin A and cyclosporin 0.05% eye drops for treatment of dry eye syndrome

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| **Submission date**<br>04/08/2008 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[_] Results<br>[_] Individual participant data<br>[_] Record updated in last year |
| **Registration date**<br>08/08/2008 | **Overall study status**<br>Completed | |
| **Last Edited**<br>08/08/2008 | **Condition category**<br>Eye Diseases | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
Prof Choun-Ki Joo

**Contact details**
Department of Ophthalmology
KangNam St. Mary's Hospital
505 Ban-Po Dong, Seocho-Ku
Seoul
Korea, South
137-040

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
N/A

## Study information

## Scientific Title

## Study objectives
The aim of this study is to compare the efficacy and safety of vitamin A (retinyl palmitate 0.05%) and cyclosporin A ([CsA] 0.05%) eye drops in treating patients with dry eye disease.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Ethics approval received from the Institutional Review Board of KangNam St. Mary's Hospital (South Korea) on the 14th December 2006.

## Study design
Prospective, randomised, controlled, parallel group 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
Bilateral dry eye syndrome/ophthalmology

## Interventions
150 patients (300 eyes) with dry eye were divided into three groups: vitamin A (N = 50), cyclosporin A (N = 50) and control (N = 50). Patients were treated twice daily with cyclosporin A 0.05%, four times daily with retinyl palmitate (vitamin A) 0.05%, or with no eye drops. Adjunctive treatment with preservative-free artificial tears was undertaken four times a day in all groups.

Total duration of treatment for each patient was three months, and total duration of follow-up was also three months, making a total of 6 months duration.

## Intervention Type
Supplement

## Phase
Not Specified

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

Vitamin A (retinyl palmitate), cyclosporin A (CsA)

### Primary outcome measure
1. Symptom scoring
2. Tear film BUT
3. Schirmer test (without anaesthesia)
4. Corneal fluorescein staining
5. Conjunctival impression cytologic analysis

All performed before treatment, and at first, second and third months after initiation of treatment.

### Secondary outcome measures
Goblet cell density, assessed before treatment, and at first, second and third months after initiation of treatment.

### Overall study start date
27/12/2006

### Completion date
14/06/2007

## Eligibility

### Key inclusion criteria
1. Signed informed consent
2. Male and female patients aged 21 years and over
3. Diagnosis of dry eye syndrome refractory to conventional management
4. Schirmer test (without anaesthesia) was less than 5 mm/5 minutes in at least one eye
5. Low tear film break-up time (tBUT) (less than 5 seconds)
6. Mild superficial punctate keratitis, defined as a corneal punctate fluorescein staining score of greater than or equal to 1 in either eye (scale 0 [none] to 3 [severe])
7. Symptoms of ocular irritation as assessed by an Ocular Surface Disease Index (OSDI) score of 25 or greater (on a scale of 0 - 59)

### Participant type(s)
Patient

### Age group
Adult

### Sex
Both

### Target number of participants
150 patients (300 eyes)

### Key exclusion criteria
1. History of any ocular disorder including injury
2. Ocular infection

3. Non-dry eye ocular inflammation
4. Ocular trauma
5.Ocular surgery within the prior 6 months

### Date of first enrolment
27/12/2006

### Date of final enrolment
14/06/2007

## Locations

### Countries of recruitment
Korea, South

### Study participating centre
**Department of Ophthalmology**
Seoul
Korea, South
137-040

## Sponsor information

### Organisation
The Catholic University of Korea (South Korea)

### Sponsor details
Department of Ophthalmology and Visual Science
College of Medicine
KangNam St. Mary's Hospital
505 Ban-Po Dong, Seocho-Ku
Seoul
Korea, South
137-040

### Sponsor type
University/education

### Website
http://www.catholic.ac.kr/

### ROR
https://ror.org/01fpnj063

# Funder(s)

**Funder type**
University/education

**Funder Name**
The Catholic University of Korea (South Korea)

**Alternative Name(s)**
The Catholic University of Korea,  , CUK

**Funding Body Type**
Private sector organisation

**Funding Body Subtype**
Universities (academic only)

**Location**
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