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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s))
Goblet cell density, assessed before treatment, and at first, second and third months after initiation of treatment.

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration