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Evaluation of symptoms and signs of evaporative dry eye with a lipid-enhanced artificial tear drop

Submission date
14/08/2024

Recruitment status
No longer recruiting

Registration date
16/08/2024

Overall study status
Completed

Last Edited
16/08/2024

Condition category
Eye Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
This study aimed to assess how well an eye drop containing propylene glycol (PG) and hydroxypropyl guar (HPG) (Systane complete) can help with dry-eye symptoms and eye health in people with evaporative dry eye (EDE).

Who can participate?
Participants in the study were adults aged 18 to 50 with EDE.

What does the study involve?
Participants were asked to use the PG-HPG eye drops three times a day for 90 days. The researchers evaluated the effectiveness of the treatment by looking at several factors, including dry eye symptoms and dry eye signs (tear osmolarity, tear meniscus height, lipid layer thickness, noninvasive tear break-up time, fluorescein tear break-up time, corneal staining and Schirmer's test I).

What are the possible benefits and risks of participating?
The potential benefits include personalized evaluation of the ocular surface performed during the study, which allows for tailored assessment of the disease and the provision of Systane Complete treatment free of charge to participants. Possible adverse effects may include transient discomfort from some of the tests, such as eye irritation or a sensation of a foreign body, but these symptoms are generally short-lived.

Where is the study run from?
Centro de la Vision (Chile)

When is the study starting and how long is it expected to run for?
December 2022 to March 2024

Who is funding the study?
Alcon Laboratories (USA)

Who is the main contact?
Dr Cristián Cartes, ccartesindo@gmail.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil Known

Protocol serial number
Nil known

Study information

Scientific Title
Effect of a propylene glycol-hydroxypropyl guar nanoemulsion in symptoms and ocular surface parameters in patients with evaporative dry-eye

Study objectives
The use of propylene glycol-hydroxypropyl guar nanoemulsion teardrop improves dry eye symptoms in patients with evaporative dry eye

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 15/12/2022, Centro de la Vision Ethics Committee (Camino el Alba 9500, Santiago, 7600830, Chile; +56 233030000; hborel@centrodelavision.cl), ref: NA

Study design
Single-center interventional pre-post design

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Evaporative dry eye

Interventions
Participants were instructed to instill propylene glycol-hydroxypropyl guar nanoemulsion (Systane Complete) in both eyes three times a day for 90 days.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Systane Complete

Primary outcome(s)
Dry eye symptoms (Ocular surface disease index questionnaire; OSDI) at baseline, 1 month, and 3 months

Key secondary outcome(s))
1. Tear break-up time and corneal staining (National Eye Institute scale) were assessed at baseline and at 3 months
2. Osmolarity (measured in mosm/L) was evaluated at baseline and at 3 months using the TearLab Osmometer
3. Lipid layer thickness (categorized as normal/mild/moderate/severe), non-invasive tear break-up time (measured in seconds), and tear meniscus were assessed at baseline and at 3 months using the Keratograph 5M device

Completion date
30/03/2024

Eligibility

Key inclusion criteria
1. 18 and 50 years
2. Symptomatic dry-eye disease, according to (Dry eye workshop II) DEWS II criteria

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
50 years

Sex
All

Total final enrolment
30

Key exclusion criteria
1. Contact lens wearers
2. Previous ocular surgery
3. History of major systemic or ocular conditions
4. Active ocular inflammation or inflammatory and autoimmune conditions (I.E. ocular cicatricial pemphigoid, Sjögren’s disease)
5. Glaucoma medications or other concomitant use of drops
6. Schirmer’s test <10 mm

Date of first enrolment
01/09/2023

Date of final enrolment
20/01/2024

Locations

Countries of recruitment
Chile

Study participating centre
Centro de la Vision
Camino el Alba 9500
Santiago
Chile
7600830

Sponsor information

Organisation

Centro de la Vision

Funder(s)

Funder type
Industry

Funder Name
Alcon

Alternative Name(s)

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan
The dataset generated during the current study will be available on request from Cristian Cartes (ccartesindo@gmail.com).

IPD sharing plan summary
Available on request