ISRCTN10208997 https://doi.org/10.1186/ISRCTN10208997

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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 16/08/2024	**Overall study status** Completed	
Last Edited 16/08/2024	**Condition category** Eye Diseases	

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

EudraCT/CTIS number
Nil Known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

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

Pharmaceutical study type(s)
Not Applicable

Phase
Phase IV

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

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

Secondary outcome measures
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

Overall study start date
15/12/2022

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
50 Years

Sex
Both

Target number of participants
30

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
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7600830

Sponsor information

Organisation
Centro de la Vision

Sponsor details
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Sponsor type
Hospital/treatment centre

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

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
30/09/2024

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