

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 16/08/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 16/08/2024	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

Contact name

Dr Cristian Cartes

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil Known

ClinicalTrials.gov (NCT)

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