

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

<b>Submission date</b> 14/08/2024	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 16/08/2024	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 16/08/2024	<b>Condition category</b> Eye Diseases	<input type="checkbox"/> Individual participant data <input checked="" 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

### ORCID ID

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### Contact details

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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

Chile

7600830

# Sponsor information

## Organisation

Centro de la Vision

## Sponsor details

Camino el Alba 9500

Santiago

Chile

7600830

+56 23303000

msrur@centrodelavision.cl

## 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