

# Dry eye and ocular surface parameters after 25 G pars plana vitrectomy

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<b>Registration date</b> 27/08/2025	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 07/07/2025	<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 looks at whether a type of eye surgery called pars plana vitrectomy (PPV) might cause or worsen Dry Eye Disease (DE). DE is a common condition that makes eyes feel dry, irritated, or uncomfortable. While other eye surgeries like LASIK and cataract surgery are known to affect the eye's surface and lead to dry eye, the impact of PPV—especially when done with small incisions—hasn't been studied much.

Researchers are focusing on how PPV affects certain cells and proteins in the eye that help keep it moist and comfortable. They're also comparing results between people with and without diabetes, since diabetes can increase the risk of eye problems after surgery.

### Who can participate?

People who are scheduled to have PPV surgery may be eligible to take part in the study. Participation is completely voluntary.

### What does the study involve?

Participants will have simple, non-invasive eye tests before and after their surgery. These tests are safe and don't affect vision.

After surgery, all participants will use two types of eye drops:

- An antibiotic (Moxifloxacin) four times a day for one week

- A steroid (Prednisolone acetate), gradually reduced over 6–8 weeks

In addition, participants will be randomly assigned to either receive or not receive artificial tears (a mix of trehalose and hyaluronic acid) four times a day.

### What are the possible benefits and risks of participating?

There are no extra medical risks beyond those normally associated with PPV surgery. The tests used in the study are safe and non-invasive.

While participants may not directly benefit, the study could help improve understanding of how to protect the eye's surface during and after surgery.

### Where is the study run from?

Oftamedica (Chile)

When is the study starting and how long is it expected to run for?  
July 2021 to October 2024.

Who is funding the study?  
TheaLab (Chile)

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

### EudraCT/CTIS number

Nil known

### IRAS number

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

Nil known

## Study information

### Scientific Title

Dry eye and ocular surface parameters after 25 G pars plana vitrectomy

### Study objectives

Small incision Pars Plana Vitrectomy PPV triggers/worsens dry eye disease.

### Ethics approval required

Ethics approval required

**Ethics approval(s)**

Approved 16/06/2021, Comité de Ética Servicio de Salud Araucanía Sur (Andres Bello 636, Temuco, 9630000, Chile; +56 45 255 7064; comite.etica@asur.cl), ref: OF162

**Study design**

Interventional randomized controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

No participant information sheet available

**Health condition(s) or problem(s) studied**

Evaluation of dry eye after 25G pars plana vitrectomy

**Interventions**

All patients underwent 25G pars plana vitrectomy and received the same postoperative regimen: topical moxifloxacin four times daily for one week, and topical prednisolone acetate 1%, tapered over 6–8 weeks.

Patients were randomized in a 1:1 ratio using Stata 15.0 statistical software to receive either standard postoperative care alone or standard care plus artificial tears containing 3% trehalose and 0.15% hyaluronic acid, administered four times daily for three months.

Both groups were followed for a total of three months. This was an open-label study.

**Intervention Type**

Procedure/Surgery

**Primary outcome measure**

Dry eye symptoms were measured using the Ocular Surface Disease Index (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, 1 month 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 Lacrydiag device

4. Evaluation of Conjunctival Impression Cytology after small incision Pars Plana Vitrectomy (Nelson Scale and Mucins) at baseline and 3 months after surgery

**Overall study start date**

16/06/2021

**Completion date**

10/10/2024

## **Eligibility**

**Key inclusion criteria**

1. Consecutive patients over 18 years old who will undergo PPV 25 G by a single surgeon (PM) for Diabetic retinopathy or other causes (i.e. macular hole, epiretinal membrane)
2. Availability to attend Ocular Surface evaluation previous to retinal surgery.
3. Over 18 years old who signed informed consent.

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

50

**Total final enrolment**

57

**Key exclusion criteria**

1. Previous refractive surgery (LASIK/PRK)
2. Patients under glaucoma medication
3. Contact lens wearers
4. Eye surgery in the last 3 months
5. Patients who require conjunctival opening
6. Active inflammation and Inflammatory and autoimmune conditions (I.E Ocular Cicatricial Pemphigoid, Sjogren Disease)

**Date of first enrolment**

01/07/2021

**Date of final enrolment**

20/10/2024

## Locations

### Countries of recruitment

Chile

### Study participating centre

Oftamedica

Av Alemania 450

Temuco

Chile

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## Sponsor information

### Organisation

Oftamedica

### Sponsor details

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### Sponsor type

Hospital/treatment centre

## Funder(s)

### Funder type

Industry

### Funder Name

Thea Lab

## Results and Publications

**Publication and dissemination plan**

Planned publication in a peer-reviewed journal.

**Intention to publish date**

01/08/2025

**Individual participant data (IPD) sharing plan**

The dataset generated during this study will be available from the Principal Investigator upon reasonable request (Cristian Cartes, ccartesindo@gmail.com).

**IPD sharing plan summary**

Available on request