ISRCTN10442132 https://doi.org/10.1186/ISRCTN10442132

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

Submission date
02/07/2025

Recruitment status
No longer recruiting

Registration date
27/08/2025

Overall study status
Completed

Last Edited
07/07/2025

Condition category
Eye Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] 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

ORCID ID
https://orcid.org/0000-0002-8121-6158

Contact details
Av Alemania 450
Temuco
Chile
4801019
+56 985007180
ccartesindo@gmail.com

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Treatment

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(s)
Dry eye symptoms were measured using the Ocular Surface Disease Index (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, 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 Citology after small incision Pars Plana Vitrectomy (Nelson Scale and Mucins) at baseline and 3 months after surgery

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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, Sjoegren 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
4801019

Sponsor information

Organisation
Oftamedica

Funder(s)

Funder type
Industry

Funder Name
Thea Lab

Results and Publications

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes