ISRCTN24398865 https://doi.org/10.1186/ISRCTN24398865

# Study evaluating a new drug for the treatment of blepharitis (eyelid inflammation) due to Demodex (mite) infestation

**Submission date**
05/05/2021

**Recruitment status**
No longer recruiting

**Registration date**
17/05/2021

**Overall study status**
Completed

**Last Edited**
23/08/2021

**Condition category**
Infections and Infestations

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

## Plain English summary of protocol

Background and study aims
Chronic blepharitis is inflammation that primarily involves the eyelid and is a common cause of eye irritation. The presence of the Demodex folliculorum mite in the eyelid structures of man has been recognized and implicated as a cause of chronic blepharitis. This interventional study was designed to evaluate the safety and efficacy of TP-03 for the treatment of blepharitis due to Demodex infestation.

Who can participate?
Males and females 18 years of age or older were randomized to the vehicle control in a previous study.

What does the study involve?
Participants will instill one drop of the active treatment solution (TP-03, 0.25%) in each eye, twice a day, morning and evening for 42 days.

What are the possible benefits and risks of participating?
Benefits include a possible reduction in the participant's cylindrical dandruff/collarette grade, mite eradication, and ocular comfort. Risks may include mild blurriness and mild burning following drop instillation.

Where is the study run from?
Asociación para Evitar la Ceguera en México I.A.P., Mexico

When is the study starting and how long is it expected to run for?
May 2019 to January 2020

Who is funding the study?
Tarsus Pharmaceuticals, Inc. (USA)

Who is the main contact?
Dr Roberto González Salinas, dr.gonzalezsalinas@gmail.com

# Contact information

### Type(s)
Scientific

### Contact name
Dr Roberto González-Salinas

### ORCID ID
https://orcid.org/0000-0001-6654-5191

### Contact details
Vicente García Torres 46
Colonia Barrio San Lucas Coyoacán
Ciudad de México
Mexico
04030
+52 442 219 9424
dr.gonzalezsalinas@gmail.com

# Additional identifiers

### Protocol serial number
TRS-005

# Study information

### Scientific Title
Single arm, open-label trial to evaluate the safety and efficacy of TP-03 for the treatment of blepharitis due to Demodex infestation

### Study objectives
Treatment with TP-03 will result in a cure, defined as 2 or fewer collarettes for the upper eyelid of the analysis eye at the completion of treatment, for a statistically significant proportion of the participants.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Approved 11/05/2019, APEC Ethics Committee of the Association to Prevent Blindness in Mexico (Vicente Garcia Torres No. 46, Colonia Barrio San Lucas, Coyoacan, Ciudad de Mexico, Mexico, 04030; +55 1084 1400; comunicacion@apec.com.mx), ref: TRS-005

### Primary study design

Interventional

### Study design
Prospective single arm open-label treatment single centre study

### Study type(s)
Treatment

### Health condition(s) or problem(s) studied
Blepharitis due to Demodex infestation

### Interventions
Participants will instill one drop of the active treatment solution (TP-03, 0.25%) in each eye, twice a day, morning and evening for 42 days.

Participants will be seen for follow-up visits at Days 7, 14, 28 and 42.

Assessments of collarettes by slit lamp examination and Demodex density, measured by lash epilation and mite counting by microscope, will be conducted at visit Days 14, 28 and 42. Safety will be determined by assessing any adverse effects related to treatment as well as assessing any changes in visual acuity and slit lamp biomicroscopy findings.

### Intervention Type
Drug

### Phase
Phase II

### Drug/device/biological/vaccine name(s)
TP-03 lotilaner ophthalmic solution 0.25%

### Primary outcome(s)
Signs of blepharitis measured using collarette grading at Days 7, 14, 28, and 42

### Key secondary outcome(s)
Demodex density measured by lash epilation and mite counting via microscope at Days 7, 14, 28, and 42

### Completion date
20/01/2020

## Eligibility

### Key inclusion criteria
1. Subjects greater or equal to 18 years of age with blepharitis due to Demodex infestation
2. Willing to sign the informed consent and deemed capable of complying with the requirements of the study protocol
3. Participants must meet the following criteria in at least one eye: Have more than 10 collarettes present on the upper lid or an average Demodex density, upper and lower eyelids combined, of at least 1.5 mites per lash

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 Years

### Sex
All

### Total final enrolment
18

### Key exclusion criteria
1. Systemic or topical antibacterial, antiparasitic or anti-inflammatory steroid treatment within the last 14 days
2. Topical tea tree oil or hypochlorous acid treatment of the ophthalmic area within the last 14 days
3. The use of lid hygiene products (lid scrubs) within the last 14 days or unwilling to forego the use of lid hygiene products during the study treatment phase
4. Contact lens wear within the last 7 days or unwilling to forego contact lens wear during the study treatment phase

### Date of first enrolment
11/11/2019

### Date of final enrolment
25/11/2019

## Locations

### Countries of recruitment
Mexico

### Study participating centre
**Asociación para Evitar la Ceguera en México I.A.P.**
Vicente García Torres 46
Colonia Barrio San Lucas Coyoacán
Ciudad de México
Mexico
04030

# Sponsor information

### Organisation
Tarsus Pharmaceuticals, Inc.

# Funder(s)

### Funder type
Industry

### Funder Name
Tarsus Pharmaceuticals, Inc.

# Results and Publications

### Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

### IPD sharing plan summary
Data sharing statement to be made available at a later date

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | | 20/08/2021 | 23/08/2021 | Yes | No |