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

Clinical Trials Information System (CTIS)
Nil known

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

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

Primary study design
Interventional

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