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Study evaluating a new drug to treat participants with Demodex blepharitis (inflammation of the eyelids)

Submission date
18/02/2021

Recruitment status
No longer recruiting

Registration date
11/03/2021

Overall study status
Completed

Last Edited
11/03/2021

Condition category
Eye Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The purpose of this study is to evaluate the safety and efficacy of an eyedrop treatment for a condition known as blepharitis, which causes inflammation of the eye and dry eyes, due to infestation with the Demodex mite, which lives in the eyelashes.

Who can participate?
Adult participants with blepharitis due to Demodex infestation.

What does the study involve?
Participants will be allocated to one of two groups, with an equal chance of being in either group (like tossing a coin). Participants and researchers will not have a choice in the treatment given and participants will not know which treatment they have received during the study period. The first group of participants will receive the study drug TP-03 eyedrops and the second of participants will receive eyedrops that appear identical but do not contain active ingredients. Participants will be asked to apply the treatment they have received to each eye, twice a day, for 28 days.

What are the possible benefits and risks of participating?
Participants who receive the study drug may experience an improvement in their symptoms of eye inflammation. Participants who do not receive the study drug may not receive any direct benefit.

Potential risks for participation in this study include eye irritation (redness and/or inflammation) due to either the study drug or the inactive treatment.

Where is the study run from?
Asociacion para Evitar la Ceguera (APEC) Departamento de lnvestigacion (Mexico)

When is the study starting and how long is it expected to run for?
From March 2019 to August 2019

Who is funding the study?
Tarsus Pharmaceuticals (USA)

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

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
TRS-004

Study information

Scientific Title
Randomized, vehicle controlled, double-blind, parallel trial to evaluate the safety and efficacy of TP- 03 for the treatment of blepharitis due to Demodex infestation (Jupiter)

Acronym
Jupiter

Study objectives

Treatment with TP-03 will result in a significant decrease from baseline in Demodex density (mites/lash) at day 28 compared to the vehicle control. Any ocular irritation experienced will be mild and similar to the vehicle control in frequency and severity.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 05/03/2019, Ethics and Research Committee, Asociacion para Evitar la Ceguera en Mexico I.A P. (Association to Prevent Blindness in Mexico I.A P., Vicente Garcia Torres 46, Colonia Barrio San Lucas Coyoacan, Ciudad de Mexico 04030; +52 10 84 14 00; no email address provided), ref: none provided

Study design
Prospective double-masked single-centre randomized parallel vehicle-controlled study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Eyelid inflammation due to a parasitic (Demodex) infestation

Interventions
This study is intended to evaluate the safety and efficacy of TP-03, ophthalmic solution, 0.25% compared to vehicle control for the treatment of blepharitis due to Demodex infestation.

Participants will be randomized 1:1 in the active and control arms and will use the study drug twice a day for 28 days. A computer-generated block randomization schedule will be used to label the study drug and bottles will be assigned to participants on a consecutive basis.

Participation in the study will last for up to 90 days post-initiation of treatment.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
TP-03 (topical ophthalmic preparation of lotilaner)

Primary outcome(s)
Change in Demodex density calculated as the number of mites per lash measured using lash epilation and mite counting via microscope at baseline and 28 days

Key secondary outcome(s))
Change in collarette grading measured using slit lamp biomicroscopy at baseline, 14, and 28 days

Completion date
19/08/2019

Eligibility

Key inclusion criteria
1. Willing to sign the informed consent and deemed capable of complying with the requirements of the study protocol
2. Participants must meet all of the following criteria in at least one eye:
2.1. More than 10 collarettes present on the upper lid
2.2. Mild to severe lid margin erythema
2.3. Average Demodex density of 1.5 or more mites per lash
3. Aged ≥18 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
60

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. Use of lid hygiene products (eyelid scrubs) in the last 14 days or unwilling to forego the use of lid hygiene products during the study

Date of first enrolment
07/03/2019

Date of final enrolment
25/04/2019

Locations

Countries of recruitment

Mexico

Study participating centre
Asociacion para Evitar la Ceguera (APEC) Departamento de lnvestigacion
Vicente Garcia Torres 46
Colonia Barrio San Lucas
Coyoacan
Ciudad de Mexico
Mexico
04030

Sponsor information

Organisation
Roberto Gonzalez Salinas, MD

Funder(s)

Funder type
Industry

Funder Name
Tarsus Pharmaceuticals

Results and Publications

Individual participant data (IPD) sharing plan
There is no plan to share participant-level data as the investigational product data has not yet been submitted to a regulatory authority.

IPD sharing plan summary
Not expected to be made available