

Long-term safety of TP-03 treatment for Demodex blepharitis

Submission date 02/03/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 09/03/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 09/03/2021	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Chronic blepharitis is eye inflammation that mainly involves the eyelid margin and is a common cause of chronic eye irritation. Blepharitis may affect the eyelid skin, base of the eyelashes, the eyelash follicles, the meibomian glands and gland orifices. The presence of the mite *Demodex folliculorum* in the eyelid structures of humans has been recognized for more than a century and has been implicated as a cause of chronic blepharitis. This study is designed to assess the long-term safety of the use of TP-03, 0.25% or its vehicle for the treatment of Demodex blepharitis.

Who can participate?

Patients aged 18 or older who have blepharitis due to Demodex infestation

What does the study involve?

Up to 418 participants who completed treatment with TP-03, 0.25% or its vehicle for 43 days will be invited to participate in this observational study. No treatment will be given in this study. Safety will be determined by assessing adverse events as well as evaluating any changes in eye tests.

What are the possible benefits and risks of participating?

This is an observational study and no treatment will be given. Participants may not receive any direct benefit. Possible risks include the dye used for the eye test causing mild irritation and temporary color changes to the tears and mucous. The eye tests may also cause mild irritation to the eye surface and temporary blurred vision, and there is a rare risk of an allergic reaction to the topical anesthetic.

Where is the study run from?

Ora, Inc. (USA)

When is the study starting and how long is it expected to run for?

July 2020 to February 2022

Who is funding the study?

Tarsus Pharmaceuticals, Inc. (USA)

Who is the main contact?

Yesha Raval

yraval@oraclinical.com

Contact information

Type(s)

Public

Contact name

Ms Yesha Raval

Contact details

300 Brickstone Square

Andover

United States of America

01810

+1 (0)978 685 8900

yraval@oraclinical.com

Type(s)

Scientific

Contact name

Ms Stephanie Baba

Contact details

15440 Laguna Canyon Road

Suite 160

Irvine

United States of America

92618

+1 (0)510 435 0090

stephanie@tarsusrx.com

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

TRS-011

Study information

Scientific Title

Extended observational trial to evaluate the long-term safety of TP-03 following acute treatment for Demodex blepharitis

Study objectives

The Saturn-1 extension study is an observational study to evaluate the long-term safety of acute administration of TP-03, 0.25% for the treatment of Demodex blepharitis.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 11/01/2021, Alpha IRB (1001 Avenida Pico, Suite C, #497, San Clemente, CA 92673, USA; +1(0)949 542 3882; info@alphairb.com), ref: 11-Jan-2021

Study design

Multicenter observational study

Primary study design

Observational

Secondary study design

Longitudinal study

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied

Blepharitis due to Demodex infestation

Interventions

A post-treatment observational study to follow participants who were previously treated for 43 days with TP-03, 0.25% or its vehicle. Participants will be assessed at 180 and 365 days following the initiation and completion of treatment in order to assess the long-term safety of acute administration of TP-03, 0.25% for the treatment of Demodex blepharitis. Safety will be determined by assessing adverse events as well as evaluating any changes in visual acuity, slit-lamp biomicroscopy including an assessment of corneal staining, intraocular pressure and a dilated fundus examination. No treatment will be administered in this study.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

TP-03

Primary outcome measure

Adverse events assessed using participant response to non-specific queries, spontaneous participant reports and investigator observations at Day 180 and Day 365

Secondary outcome measures

Measured at baseline, Day 180 and Day 365:

1. Visual acuity measured using ETDRS-Fast method
2. Anterior segment health assessed using slit-lamp biomicroscopy
3. Intraocular pressure measured using applanation tonometry
4. Posterior segment health assessed using dilated fundus examination

Overall study start date

02/07/2020

Completion date

28/02/2022

Eligibility

Key inclusion criteria

1. Male or female, aged ≥ 18 years of age
2. Participants must have been treated with TP-03 or the vehicle of TP-03 for 43 days
3. Be willing to sign IRB-approved informed consent and deemed capable of complying with the requirements of the study protocol
4. Be willing to forego participation in any clinical trial with an investigational drug or device during the observational study

Participant type(s)

Patient

Age group

Mixed

Lower age limit

18 Years

Sex

Both

Target number of participants

418

Key exclusion criteria

The investigator has the right to exclude any individual from participating in the study if s/he deems it in the best interest of the participant or if the participant's enrollment could impact data validity

Date of first enrolment

02/03/2021

Date of final enrolment

31/08/2021

Locations

Countries of recruitment

United States of America

Study participating centre**Eye Research Foundation**

520 Superior Ave, Suite 235

Newport Beach

United States of America

92663

Study participating centre**Andover Eye Associates**

138 Haverhill Street, Suite 201

Andover

United States of America

01810

Study participating centre**Midwest Cornea Associates, LLC**

10300 N. Illinois Street, Suite 1020

Carmel

United States of America

46290

Study participating centre**The Eye Care Institute**

1536 Story Avenue

Louisville

United States of America

40206

Study participating centre

Piedmont Eye Center
116 Nationwide Drive
Lynchburg
United States of America
24502

Study participating centre
Cornea and Cataract Consultants of Arizona
3815 E. Bell Road, Suite 2500
Phoenix
United States of America
85032

Study participating centre
Vita Eye Clinic
222 N. Lafayette St. Suite 12
Shelby
United States of America
28150

Study participating centre
Oculus Research, Inc. at Eyecare Center
4170 Fayetteville Rd
Raleigh
United States of America
27603

Study participating centre
Vision Institute
320 East Fontanero Street, Suite 201
Colorado Springs
United States of America
80907

Study participating centre
Total Eye Care, P.A.
6060 Primacy Parkway, Suite 200
Memphis
United States of America
38119

Study participating centre
Scott & Christie and Associates, PC
105 Brandt Drive, Suite 201
Cranberry Township
United States of America
16066

Study participating centre
Visionary Eye Institute
361 Hospital Rd, #324
Newport Beach
United States of America
92663

Study participating centre
Ophthalmology Associates
12990 Manchester Road, Suite 200
St. Louis
United States of America
63131

Study participating centre
Michael Washburn Center for Ophthalmic Research LLC
901 E. 86th St.
Indianapolis
United States of America
46240

Study participating centre
Alpine Research Organization
124 South Fairfield Road, Suite C
Layton
United States of America
84041

Sponsor information

Organisation

Tarsus Pharmaceuticals, Inc.

Sponsor details

15440 Laguna Canyon Road
Ste 160
Irvine
United States of America
92618
+1 (0)9494099820
info@tarsusrx.com

Sponsor type

Industry

Website

<https://tarsusrx.com/>

Funder(s)**Funder type**

Industry

Funder Name

Tarsus Pharmaceuticals, Inc.

Results and Publications**Publication and dissemination plan**

Planned publication in a peer-reviewed journal. No additional documents are or will be available.

Intention to publish date

28/02/2023

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available as this is data for an investigational product that has not yet been submitted to a regulatory authority.

IPD sharing plan summary

Not expected to be made available