ISRCTN49009434 https://doi.org/10.1186/ISRCTN49009434

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

Submission date	Recruitment status	[ ] Prospectively registered
02/03/2021	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
09/03/2021	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
09/03/2021	Eye Diseases	[ ] 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

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
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

Study type(s)
Treatment

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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Sex
All

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.

Funder(s)

Funder type
Industry

Funder Name
Tarsus Pharmaceuticals, Inc.

Results and Publications

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