

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

<b>Submission date</b> 02/03/2021	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 09/03/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 09/03/2021	<b>Condition category</b> 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

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## Contact information

### Type(s)

Public

### Contact name

Ms Yesha Raval

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Scientific

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

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  $\geq 18$  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  
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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