

# Can eye drops effectively treat dry eye disease?

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<b>Registration date</b> 04/03/2019	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 11/08/2021	<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

Dry eye disease or dry eye syndrome is a multifactorial and complex disorder of the tears and ocular surface which occurs when the quantity or quality of tears fails to maintain adequate lubrication of the surface of the eye. Dry eye incidence increases with age and prevalence ranges from 5% to 35% of the adult population depending on the definition of dry eye utilised. Dry eye is a frequently encountered ocular morbidity with 25% of patients who visit ophthalmic clinics report symptoms of dry eye. There are multiple therapeutic options available for dry eye, many of which aim to help lubricate the ocular surface and hence reduce the symptoms of dry eye, however not all patients respond favourably to the prescribed treatments.

Hydroxypropyl-Beta-Cyclodextrin is a soluble, benign, safe and well characterised cyclodextrin that is accepted as an approved excipient of drug formulations, including eye drops, across Europe. Current research suggests Hydroxypropyl-Beta-Cyclodextrin is a suitable molecule for treating the symptoms of dry eye, however due to gaps in the literature this hypothesis remains unconfirmed.

This clinical investigation is aiming to establish the safety and performance characteristics of the medical device Hydroxypropyl-Beta-Cyclodextrin 10% w/v Eye Drops (preservative free), indicated for the relief of dry eye sensations.

The development of Hydroxypropyl-Beta-Cyclodextrin 10% w/v as a novel dry eye drop may provide a safe, efficacious and cost-effective alternative treatment for patients suffering from dry eye.

### Who can participate?

Healthy volunteers aged over 50 with mild to moderate dry eye.

### What does the study involve?

The study involves application of one drop of Hydroxypropyl-Beta-Cyclodextrin 10% w/v eye drops to each eye two or three times daily, or as required over the course of the six month trial. Patients will be requested to complete a daily diary, a questionnaire and to visit to the centres each month where information is collected including but not limited to Schirmer's test, Tear Film Break-up Time and OCT scan.

What are the possible benefits and risks of participating?

Patients mild to moderate dry eye sensations may be alleviated by using Hydroxypropyl-Beta-Cyclodextrin 10% w/v eye drops as part of this study, but this cannot be guaranteed. Patients may experience some side effects from this treatment such as mild eye irritation.

Where is the study run from?

Moorfields Eye Hospital NHS Foundation Trust (UK)

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

The study is planned to begin during summer 2019 and run for six months

Who is funding the study?

Warneford Healthcare Limited

Who is the main contact?

Prof. Sobha Sivaprasad

## Contact information

**Type(s)**

Scientific

**Contact name**

Prof Sobha Sivaprasad

**ORCID ID**

<https://orcid.org/0000-0001-8952-0659>

**Contact details**

Moorfields Eye Hospital

162 City Rd

London

United Kingdom

EC1V 2PD

**Type(s)**

Public

**Contact name**

Dr Stephanie Tweed

**Contact details**

Unit 4, Rotherbrook Court

Bedford Road

Petersfield

United Kingdom

GU32 3QG

## Additional identifiers

**Protocol serial number**

TF02S-CIP

## Study information

**Scientific Title**

A clinical trial to investigate the clinical performance and safety of Hydroxypropyl-Beta-Cyclodextrin 10% w/v Eye drops In the treatment of dry eye disease

**Acronym**

THEIA

**Study objectives**

Hydroxypropyl-Beta-Cyclodextrin 10% w/v Eye Drops is effective in the treatment of dry eye disease.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 24/05/2019, Ethics board: London - Bromley Research Ethics Committee (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; Tel: +44 (0)207 104 8063; Email: nrescommittee.london-bromley@nhs.net), REC ref: 19/LO/0623

**Study design**

Single-centre single-arm open-label investigation

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Dry Eye Disease

**Interventions**

The study is a single arm design, therefore randomisation is not applicable.

All participants will be treated with the Hydroxypropyl-Beta-Cyclodextrin 10% w/v Eye Drops, with 1 drop administered to the affected eye twice daily, or whenever required.

The total duration of treatment is 6 months. Participants will start treatment at a baseline visit (0 month) at the study centre and participants will visit the study centre at 1, 3 and 6 months (end of treatment).

**Intervention Type**

Device

**Primary outcome(s)**

1. Safety of HPBCD treatment will be assessed by:
  - 1.1. Recording symptoms and adverse events during each clinical follow up.
  - 1.2. A full ocular exam with Optical Coherence Tomography (OCT) at each clinical follow up.
2. Clinical performance outcome will be measured using patient questionnaire answers regarding a change in baseline for dry eye symptoms at each clinical follow up.

### **Key secondary outcome(s)**

1. Quality of life will be measured using patient questionnaire answers at each clinical follow up.
2. Symptoms of dry eye disease will be measured using:
  - 2.1. Tear film break-up time (TBUT) at each clinical follow up.
  - 2.2. Schirmer's test at each clinical follow up.
3. Ease of use of the device (in line with the instructions for use) will be measured using patient questionnaire answers at each clinical follow up.

### **Completion date**

12/09/2020

### **Reason abandoned (if study stopped)**

Social isolation measures

## **Eligibility**

### **Key inclusion criteria**

1. Over 50 years of age.
2. Mild to moderate dry eye.
3. Life expectancy of more than 6 months' (length of study).
4. Ability to return for study visits.

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

All

### **Total final enrolment**

11

### **Key exclusion criteria**

1. Current smoker.
2. Known to suffer from an allergy or hypersensitivity to any of the components within the medical device.
3. Taking any other eye drops for dry eye.
4. Taking any other eye drops containing cyclodextrin.

5. Has used contact lenses within the last 4-7 days.
6. Has dry eye secondary to eyelid malposition, corneal dystrophy, ocular neoplasia, filamentous keratitis, corneal neovascularisation or orbital radiotherapy, or a history of ocular disease including traumatism, infection, inflammation, allergy, or herpes within the last 3 months.
7. History of inflammatory corneal ulcer or uveitis within the last 12 months.
8. Has allergic rhinitis that is current or susceptible to reactivation during the study
9. Has had cataract or corneal surgery in the last 12 months.
10. Currently participating in any other clinical trial or has participated in another clinical trial within 3 months prior to the screening/baseline visit.
11. Not physically able to perform study procedures.
12. History of drug/alcohol abuse, mental dysfunction or other factors limiting their ability to cooperate fully.
13. Has any other condition, which in the opinion of the investigator, would make the subject not a suitable candidate for the study.

**Date of first enrolment**

12/09/2019

**Date of final enrolment**

12/03/2020

## **Locations**

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Moorfields Eye Hospital**

162 City Road

London

United Kingdom

EC1V 2PD

## **Sponsor information**

**Organisation**

Warneford Healthcare Ltd.

## **Funder(s)**

**Funder type**

Industry

## Funder Name

Warneford Healthcare Ltd.

# Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

## IPD sharing plan summary

Other

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Basic results</a>	version 1.0	08/06/2021	11/08/2021	No	No
<a href="#">HRA research summary</a>			28/06/2023	No	No