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Can eye drops effectively treat dry eye disease?

Submission date 18/01/2019	**Recruitment status** Stopped	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [X] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 04/03/2019	**Overall study status** Stopped	
Last Edited 11/08/2021	**Condition category** Eye Diseases	

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
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Type(s)
Public

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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

Primary study design
Interventional

Study design
Single-centre single-arm open-label investigation

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?
Basic results	version 1.0	08/06/2021	11/08/2021	No	No
HRA research summary			28/06/2023	No	No