ISRCTN17861788 https://doi.org/10.1186/ISRCTN17861788

Evaluation of 0.18% HA emulsion eyedrop for moderate to severe dry eye

Submission date	Recruitment status	[_] Prospectively registered
02/12/2019	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/12/2019	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
18/03/2025	Eye Diseases	

Plain English summary of protocol

Background and study aims

Dry eye or meibomian gland dysfunction (MGD) is a complex condition for which numerous management products have been developed to deal with the many causes of the condition. Dry eye has significant impact on quality of life and is a burden. 0.18% emulsion CE-marked eyedrop manufactured by Horus Pharma has the potential to provide dry eye relief for moderate to severe dry eye based on the composition of the eyedrop.

The purpose of this study is to evaluate eyedrop performance and its beneficial effect in people with moderate to severe dry eye problems after one month of daily use. There are two phases of the study. The first phase is to determine the effect of a single instillation of the eyedrop over a two-hour period. The second phase is to determine the eyedrop effect after repeated daily use over a one-month duration.

Who can participate?

Adults who are between 18 to 75 years old, healthy, currently not wearing contact lenses or using the study eyedrop and have moderate to severe dry eye signs and symptoms.

What does the study involve?

Participants will be given eye drops to use instead of their usual eye drops for one month.

What are the possible benefits and risks of participating?

Participants may not directly benefit from taking part in this study but will have the opportunity to try a different eyedrop to manage their dry eye condition and will also receive a free examination of the front part of their eyes and free supply of the study product during their participation in the study. Due to the nature and short duration of the study, the risks of participating are considered minimal.

Where is the study run from?

Ocular Technology Group - International (UK)

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

November 2019 to June 2020

Who is funding the study?
Laboratoires Horus Pharma, France

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
272716

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
ID19-42/ HPCLIDM052019003, IRAS 272716

Study information

Scientific Title
0.18% HA emulsion Characterisation of Clinical Performance and Acceptance

Study objectives
Phase 1 of this study is an exploratory study hence no hypothesis will be tested
Phase 2: After one-month use of eyedrop the overall subjective ocular comfort visual analog scale (VAS) score rating and ocular surface status will improve for the overall study population, irrespective of the dry eye etiology

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/11/2019, East of England - Cambridge Central Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207 104 8234; NRESCommittee.EastofEngland-CambridgeCentral@nhs.net), ref 19/EE/0315

Study design
Interventional non-randomised single centre study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Dry eye/Meibomian Glands Dysfunction (MGD)

Interventions
Emulsion eyedrop containing 0.18% sodium hyaluronate, phospholipids, triglycerides and alpha lipoic targets all three layers of the tear film, as well as being hypoosmolar hence addressing the inflammatory component of dry eye.

This study will characterise the short and long-term clinical performance and acceptance of the emulsion eyedrop.

For the short term (Phase 1), the effect of a single instillation of the eyedrop before and over a two-hour period post instillation will be quantified for tear film characteristics and subjective acceptance (comfort and vision).

For the long-term (Phase 2) the effect of the repeated use of the eyedrop over a one month use period on overall subjective comfort improvement before and after use will be measured. Forty symptomatic dry eye participants will be enrolled. There will be three study visits (for phase 1 and 2) and two study visits (for phase 2 only) over a 45-day period.

Participants will need to stop using habitual eyedrops two days prior to the first study visit and during the study period. The potential participants will attend the clinic for Visit 1 to obtain informed consent and evaluate suitability to take part in the investigation. The participants will be asked to complete a series of questionnaires to capture demographics, medical & ocular

history, medications, ocular symptomatology (Ocular Surface Dryness Index - OSDI and Visual Analog Scale -VAS for eye comfort, vision and eye sensations experienced), vision measurement with spectacle correction, eye examination using a microscope and a beam of light (slit lamp). If meeting the investigation's inclusion and exclusion criteria, participants will be enrolled, baseline measurements will be performed: visual acuity, non-invasive tear film digital videos recording, tear film collection, measurement of tear film evaporation, digital eye photos and conjunctival impression.

For those in both Phase 1 and 2, the study visits are described below.
At the end of the first study visit, the next visit will be scheduled 2-5 days later.
At Visit 2 (Phase 1 test/Phase 2 dispensing visit), the study staff will place one drop of the study eyedrop into each eye. Evaluations will be performed prior to the eyedrop instillation (pre), post eyedrop instillation at multiple time points over 2-hour period. The study eyedrop will be dispensed for the participants to take home and the eyedrop will be used every day. A short secure remote electronic survey will be completed every 4 days, like the questionnaires at the clinic.
At Visit 3 (35 ±5 Days after Visit 2), the study visit will follow the same routine as Visit 1. At the end of the visit, participants will be discharged from the study.

If in Phase 2 only, the study visits are described below.
At the end of the first study visit, the study eyedrop will be dispensed to take home and the participants will need to use the study eyedrop every day. Participants will then be scheduled to return for Visit 2 about a month later (35 ±5 Days after Visit 2). A short secure remote electronic survey will be completed every 4 days, like the questionnaires at the clinic.
At Visit 2, the study visit will follow the same routine as Visit 1, involving completion of a series of questionnaires, examination of ther eyes using a microscope and a beam of light (slit lamp), and vision measurements. The same specialized measurements will be repeated and at the end of the visit, participants will be discharged from the study.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Neovis® Total Multi eyedrop

Primary outcome measure
1. Tear film characteristics using non-invasive digital recording of the tear film using the Tearscope lighting and the slit-lamp at all visits
2. Subjective comfort ratings using visual analog scale (VAS) 0-100 at all visits

Secondary outcome measures
None

Overall study start date
13/09/2019

Completion date
01/06/2020

Eligibility

Key inclusion criteria
1. Age 18 to 75 years
2. Moderate to severe dry eye sufferers defined by an OSDI score > 23
3. Be willing to stop using habitual eyedrops two days prior to the first study visit
4. Best corrected visual acuity of at least 20/30 in each eye
5. Have read and understood the Participant Information Sheet and Informed Consent in English
6. Be willing and able to adhere to the instructions set in the clinical protocol and maintain the appointment schedule

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Up to 60 symptomatic dry eye participants to be screened with a view to enroll 40 participants into the study.

Total final enrolment
40

Key exclusion criteria
1. Contact lens wearers
2. Severe ocular dryness with one of the conditions; eyelid or blinking malfunction, corneal disorders not related to dry eye syndrome, ocular metaplasia, filamentous keratitis, corneal neovascularization
3. Current user of the study products
4. Ocular anterior segment infection, inflammation, abnormality, or active disease within the last 12 months not related to dry eye that would contraindicate study participation
5. Use of systemic or ocular medications (such as isotretinoïd, cyclosporine, tacrolimus, sirolimus, pimecrolimus, punctal plugs) or dry eye therapy (intense pulse light, stem cells) that could be contraindicated as determined by the investigator
6. Monocular participants (only one eye with functional vision)
7. Any moderate or severe ocular condition observed during the slit-lamp examination at the enrolment visit
8. History of herpetic keratitis, ocular surgery or irregular cornea
9. Known pregnancy or lactation during the study period
10. Enrolment of the investigator or his/her staff, family members of the investigator, family members of the investigator’s staff, or individuals living in the households of these individuals
11. Participation in any clinical trial within 30 days of the enrollment visit

Date of first enrolment
12/11/2019

Date of final enrolment
01/05/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
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Sponsor information

Organisation
Laboratoires Horus Pharma

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Sponsor type
Industry

Website
http://www.horus-pharma.com/en/

Funder(s)

Funder type
Industry

Funder Name
Laboratoires Horus Pharma

Results and Publications

Publication and dissemination plan
Conference presentation, journal publication.

Intention to publish date
01/02/2021

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results	version V0.1	28/10/2020	19/11/2020	No	No
HRA research summary			28/06/2023	No	No
Results article		13/03/2025	18/03/2025	Yes	No