

Evaluation of an eyelid cleansing gel for dry eye management

Submission date 06/06/2018	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 07/06/2018	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 07/04/2020	Condition category Eye Diseases	☐ Individual participant data

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 a significant impact on quality of life and is a burden. Many dry eye sufferers use eyedrops to relieve their symptoms. Maintaining good eyelid hygiene with cleansing is considered a mainstay of management for MGD. Incorporating this into the participant's daily routine is beneficial. ILAST® HYDRACLEAN, 0.2% sodium hyaluronate, CE marked cleansing gel for eyelid hygiene manufactured by Horus Pharma is designed for cleaning eyelids, particularly the inflamed eyelid margin. By removing the deposits, secretions or crusts present on the eyelids and the roots of the eyelashes, the clean eyelids will lessen the dry eye symptoms. Hence, it is scientifically important to verify that the use of the study eyelid cleansing gel for dry eye sufferers produces an effect that is an improvement compared to not using it. The aim of this study is to determine the clinical performance of ILAST® HYDRACLEAN by quantifying the improvement in dry eye symptoms and meibomian gland status after four weeks using the study product.

Who can participate?

Adults who are at least 18 and who have otherwise healthy eyes with dry eye symptoms

What does the study involve?

The participants either use their usual vision correction (spectacles) throughout the study or without correction if they don't have vision correction and they continue to use their habitual eyedrops as needed. The potential participants attend the clinic for visit 1 to obtain their informed consent and evaluate their suitability to take part. If the potential participant consents to taking part, their vision and ocular (eye) integrity are assessed. The participants are asked to complete symptom questionnaires about eye comfort and dryness. If they fulfil the criteria, measurements are done, digital photographs are taken of their eyes and eyelids with and without green dye and the study product is provided. They are instructed to use the cleansing gel in the morning upon waking and at night before sleep every day for 1 month. One month later, they then attend the follow-up test/discharge visit 2 where the routine and measurements taken at visit 1 are repeated. The participants' eyes are examined with a slit-lamp biomicroscope for ocular integrity.

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 eyelid cleansing gel to manage their dry eye symptoms at no cost to them for the duration of the study. The examination and assessments of the front part of the eye are at no cost to participants and can be considered beneficial by documenting their current health status. A possible benefit may also be that using the study eyelid cleansing gel achieves better symptomatic relief to the participant than other products he/she has tried before. Due to the nature and short duration of the study, the risks of participating are considered minimal. The eyelid cleansing gel will not be instilled in the eyes but applied to the intact eyelids skin over closed eyes. This is similar to daily face washing routine. All the assessments are routine clinical procedures or specialized procedures and none present any increased risk to participants compared with normal clinical care routine.

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?

April 2018 to October 2018

Who is funding the study?

Laboratoires Horus Pharma (France)

Who is the main contact?

Mr Kishan Patel

Contact information

Type(s)

Public

Contact name

Mr Kishan Patel

Contact details

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Additional identifiers

Protocol serial number

ID18-17/HPCLIDM012018002

Study information

Scientific Title

Evaluation of an eyelid cleansing gel for meibomian glands dysfunction management

Study objectives

This in an exploratory study hence no hypothesis will be tested.

Ethics approval required

Old ethics approval format

Ethics approval(s)

London-Riverside Ethics Committee, 27/04/2018, ref: 18/LO/0810

Primary study design

Interventional

Study design

Interventional bilateral single-arm open-label 1-month dispensing study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Dry eye/meibomian glands dysfunction (MGD)

Interventions

ILAST® HYDRACLEAN sodium hyaluronate 0.2% cleansing gel for eyelid hygiene designed for cleaning eyelids, particularly the inflamed eyelid margin. By removing the deposits, secretions or crusts present on the eyelids and the roots of the eyelashes, the clean eyelids will lessen the dry eye symptoms.

The study will involve two study visits over a one-month period:

Visit 1: Enrolment/Baseline/Study Product Dispensing ~1.5 hours

Visit 2: Follow up test/discharge visit ~ 1.0 hour (30 ± 3 days from Visit 1)

The potential participants will attend the clinic for Visit 1 to obtain their informed consent and evaluate their suitability to take part in the investigation. If the potential participant consents to taking part, vision and ocular integrity will be assessed. The participants will be asked to complete the symptomatology questionnaires: Ocular Surface Dryness Index-OSDI and Visual Analog Scale-VAS for eye comfort and dryness. If they do not meet the enrollment criteria, they will be discharged. If they fulfil the investigation's inclusion and exclusion criteria, they will be enrolled, baseline measurements will be done, digital photographs of their eyes and eyelids with and without green dye will be taken and the study product dispensed. They will be instructed to rub the cleansing gel into both closed eyelids margin daily in the morning upon waking and in the evening prior to sleep every day for 1 month. The participants will either use their usual vision correction (spectacles) throughout the study or without correction if they don't have vision correction and they will continue to use their habitual eyedrops as needed.

One month later, they will then attend the follow-up test/discharge visit 2 where the routine and measurements taken at the enrolment visit 1 will be repeated. The participants' eyes will be examined with a slit-lamp biomicroscope for ocular integrity. They will be discharged from the study at the end of this visit.

Intervention Type

Supplement

Primary outcome(s)

1. Dry eye symptoms assessed using OSDI questionnaire score at all visits (baseline/dispensing and 1 month)
2. Meibomian glands status assessed using MGD scoring at all visits (baseline/dispensing and 1 month)

Key secondary outcome(s)

1. Percentage of blocked meibomian glands based on the number of blocked glands observed using slit lamp at all visits (baseline/dispensing and 1 month)
2. Eyelashes contamination grade based on the level of eyelashes contamination observed using slit lamp at all visits (baseline/dispensing and 1 month)

Completion date

15/10/2018

Eligibility**Key inclusion criteria**

1. There are no requirements as to participant race or occupation
2. At least 18 years old
3. Have read and understood the Participant Information Sheet
4. Have read, signed and dated the Informed Consent
5. Dry eye sufferers defined by an OSDI symptom score >13
6. Abnormal eyelid margin defined by:
 - 6.1. Meibomian gland dysfunction (MGD) identified by a positive MGD score of Grade 2 or higher; and/or
 - 6.2. Anterior blepharitis identified by eyelash contamination
7. Best corrected visual acuity of at least 20/30 in each eye
8. Have normal eyes with the exception of the need for visual correction
9. Be willing and able to adhere to the instructions set in the clinical protocol and maintain the appointment schedule

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Total final enrolment

30

Key exclusion criteria

1. Ocular anterior segment infection, inflammation, abnormality, or active disease that would contraindicate study participation
2. Use of systemic or ocular medications that could be contraindicated as determined by the investigator
3. Monocular participants (only one eye with functional vision)
4. Any moderate or severe ocular condition observed during the slit-lamp examination at the enrolment visit
5. History of herpetic keratitis, ocular surgery or irregular cornea
6. Known pregnancy or lactation during the study period
7. 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
8. Participation in any clinical trial within 30 days of the enrolment visit

Date of first enrolment

31/05/2018

Date of final enrolment

30/08/2018

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Ocular Technology Group - International

66 Buckingham Gate

London

United Kingdom

SW1E 6AU

Sponsor information

Organisation

Laboratoires Horus Pharma

Funder(s)

Funder type

Industry

Funder Name

Laboratoires Horus Pharma

Results and Publications

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made 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		06/04/2020	07/04/2020	No	No
HRA research summary			26/07/2023	No	No