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Evaluation of an eyelid cleansing gel for dry eye management

Submission date
06/06/2018

Recruitment status
No longer recruiting

Registration date
07/06/2018

Overall study status
Completed

Last Edited
07/04/2020

Condition category
Eye Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
66 Buckingham Gate
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United Kingdom
SW1E 6AU

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Interventional bilateral single-arm open-label 1-month dispensing 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
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 measure
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)

Secondary outcome measures
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)

Overall study start date
17/04/2018

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
35 symptomatic dry eye participants to be screened with a view to enroll 30 participants into the study

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
England

United Kingdom

Study participating centre

Ocular Technology Group - International
66 Buckingham Gate
London
United Kingdom
SW1E 6AU

Sponsor information

Organisation
Laboratoires Horus Pharma

Sponsor details
148, Avenue Georges Guynemer
Cap Var Saint-Laurent du Var
France
06700

Sponsor type
Industry

Website
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. Details to be confirmed at a later date.

Intention to publish date
15/10/2019

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