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Evaluation of the efficacy and safety of Vismed® eyedrop for the treatment of moderate to severe ocular dryness

Submission date
20/06/2018

Recruitment status
No longer recruiting

Registration date
22/06/2018

Overall study status
Completed

Last Edited
15/04/2020

Condition category
Eye Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Ocular (eye) dryness is a complex condition for which numerous management products have been developed to deal with the many causes of the condition. Ocular dryness has significant impact on quality of life and is a burden. Many ocular dryness sufferers use eyedrops to relieve their symptoms. Use of eyedrops may be beneficial and selecting the most appropriate formulation/concentration for HA eyedrop is important for long-term success. The rationale for the study is that the HA eyedrop formulation with higher concentration is likely to have the best long-term effectiveness when managing moderate and severe symptomatic dry eye sufferers. The aim of this study is to measure the effect of higher concentration HA eyedrop (test) compared to lower concentration HA eyedrop (control) on moderate to severe dry eye sufferers by assessment of their ocular surface integrity and subjective symptoms.

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 study involves four study visits (total about 4 hours) over 3.5 months. Treatment starts at Visit 2 and ends at Visit 4. The participants are required to stop any medications that they are using for dry eye and wearing contact lenses during the study period. The potential participants 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 are assessed. The investigator performs several tests and examinations to evaluate the ocular surface integrity, amount of tears, and asks the participants to complete a dry eye questionnaire. If the study investigator decides the participants qualify to take part they are told to use preservative-free artificial tears provided to them 3 to 6 times per day until they return for Visit 2 within 7 to 14 days later. They need to fill in a daily log to record the frequency of eyedrop use, other treatments and side effects. Participants then return for the second study visit. They are asked to complete the study dry eye questionnaire and the same tests as visit 1 are performed. If they do not meet the inclusion criteria, they are discharged. For the treatment phase, additional tests include lissamine green dye and symptoms questionnaire. Participants

are randomly allocated to use either the higher concentration or the lower concentration HA eyedrops. They are shown how to use the assigned eyedrop, are provided with an adequate supply of the assigned eyedrop and are scheduled to return for study visit 3 in a month. They are given another daily log.
For the third study visit, they are given the study questionnaires (dry eye and symptoms), have their vision checked and the ocular integrity assessed just like visit 2. The treatment effectiveness is rated (from very satisfying to very unsatisfying). They are provided with the assigned eyedrops to use until the next appointment as well as a new daily log. For the last /fourth study visit, the same visit routine as visit 3 is followed. They are then discharged from the study.

What are the possible benefits and risks of participating?
There is no guarantee that participants will benefit from being in this study. The participants have the opportunity to try different eyedrops to manage their dry eye problems that could produce better relief than their current eye drops at no cost to them for the duration of the study. The participants also receive a free examination of the front part of their eyes that can be considered beneficial by documenting their eyes health. Due to the nature and short duration of the study, the risks of participating are considered minimal. The risks associated with using study products are similar to those of using any marketed artificial tears or eyedrops. The product has no preservatives. All the assessments are routine clinical procedures or specialized procedures, and none present any increased risk to participants compared with normal clinical care routine. Participants will be under the care of the investigators during the study period to deal with any unexpected event. Participants will have their eye health and vision checked at the start of the study and all study visits prior to leaving the clinic to ensure that their eye integrity is maintained and their vision is unchanged.

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?
June 2018 to December 2018

Who is funding the study?
Laboratoires Horus Pharma (France)

Who is the main contact?
Kishan Patel

Contact information

Type(s)
Public

Contact name
Mr Kishan Patel

Contact details
66 Buckingham Gate
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Additional identifiers

Protocol serial number
18-30/17E4554

Study information

Scientific Title
Evaluation of the efficacy and safety of Vismed® Gel Multi 0.3% versus Vismed® Multi 0.18% on the treatment of moderate to severe ocular dryness

Study objectives
Sodium hyaluronate (Hyaluronate Acid (HA) eyedrops are used extensively in patients complaining of dry eye. Higher concentration HA eyedrops may have a greater impact than lower HA concentration eyedrops, hence better relief. The purpose of this study is to compare the efficacy and safety of Vismed 0.3% HA eyedrop (Test) with Vismed 0.18% HA eyedrop (Control) for improvement of ocular dryness signs and symptoms, on subjects with moderate to severe ocular dryness for a period of 1 and 3 months.

The aim is to demonstrate the non-inferiority of a higher concentration HA eyedrop (test: Vismed® Gel Multi 0.3%) in comparison with a lower concentration HA eyedrop (control: Vismed® Multi 0.18%) in terms of ocular (cornea and conjunctiva) staining using Oxford score on subjects with moderate to severe ocular dryness, after 3 months (84±7 days) of treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North East - Newcastle & North Tyneside 2 Ethics Committee, 19/06/2018, ref: 18/NE/0196

Study design
Interventional bilateral prospective randomized parallel-group dispensing investigator-masked multi-site study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Moderate to severe dry eye/meibomian glands dysfunction (MGD)

Interventions
80 moderate to severe dry eye sufferers will be enrolled. In the UK study site, there will be 20 subjects enrolled; 10 will be randomly assigned the Vismed 0.3% HA eyedrop (Test) eyedrops and 10 will be assigned the Vismed 0.18% HA eyedrop (Control) eyedrops for three months use.

Evaluation will include ocular staining score, dry eye questionnaire, Schirmer test, non-invasive tear break up time (NIBUT), subjective dryness symptoms, eyedrop performance and frequency of use. The investigator will be masked. Subjects will be evaluated after one and three months use of the assigned study eyedrops.

There will be four study visits (approximately ~ total 4 hours,each visit is ~ 1 hour) over a 3.5-month period.
Visit 1: Selection visit (D-14 to D -7)
Visit 2: Inclusion visit (D0)
Visit 3: One Month Follow Up (D35±3)
Visit 4: Three Months Follow Up (D84±7)
Washout period is 1 to 2 weeks (between Visit 1 and Visit 2). Treatment starts at Visit 2 and treatment period is from Visit 2 to Visit 4.

Intervention Type
Other

Primary outcome(s)
Ocular surface integrity; cornea and conjunctiva staining (Oxford score) on the worse eye between D0 and D35 (Visit 2 and Visit 3)

Key secondary outcome(s))
Comparison of D35 versus D0 and D84 versus D0 progression for test and control eyedrop and comparison between test and control eyedrop for the following parameters:
1. Cornea and conjunctiva staining (Oxford score) on worse eye
2. DEQ-5 score (5-Items Dry Eye Questionnaire)
3. Lissamine green staining score in worse eye
4. Schirmer test (tear volume) result in worse eye
5. Tear film Break-Up Time (TBUT in seconds) in worse eye
6. Ocular dryness severity symptoms (0 to 10 scale) and total score of all symptoms

Completion date
28/02/2019

Eligibility

Key inclusion criteria
There are no requirements as to participant race, gender or occupation
1. Age: more than 18 years
2. Subject with a moderate to severe dry eye syndrome needing artificial tears in the 3 months preceding the inclusion
3. Subject having used only artificial tears without preservative (NaCl 0.9%, Hydrabak®) during 1 to 2 weeks before inclusion (up to 6 times a day)
4. Subject with a score ≥ 6 for the 5-Item Dry Eye Questionnaire (DEQ-5)
5. Subject with at least one eye with:
5.1. Global ocular staining (cornea and conjunctiva) ≥4 and ≤9 (Oxford scale from 0 to 15)
AND one the following criteria:
5.2. Schirmer test ≥ 3mm/5 min and ≤9mm/ 5 min
OR
5.3. Sum of 3 measurements of Tear film Break-Up Time (TBUT) ≤ 30s
6. Have read and understood the Participant Information Sheet

7. Have read, signed and dated the Informed Consent
8. Able to comply with the study requirements, 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

Key exclusion criteria
To be eligible as a participant, each candidate shall be free of any ocular or medical condition that may affect the results of this study. The following are specific criteria that exclude a candidate from enrolment in this study:
1. Ocular anterior segment infection, inflammation, abnormality, or active disease that would contraindicate participation in the study
2 Use of systemic or ocular medications (isotretinoïd, cyclosporine, tacrolimus, sirolimus, pimecrolimus, punctual plugs) that would contraindicate participation in the study as determined by the investigator
3. Distance Best corrected visual acuity <1/10
4. Severe ocular dryness with one of these conditions:
4.1. Eyelid or blinking malfunction
4.2. Corneal disorders not related to dry eye syndrome
4.3. Ocular metaplasia
4.4. Filamentous keratitis
4.5. Corneal neovascularization
5. Had ocular surgery, including laser surgery, in either eye within the last 6 months
6. Wearing contact lenses during the study
7. Received ocular therapy (either eye) with any ophthalmic medication, except tear substitutes, within 2 weeks prior to study start or expected to receive ocular therapy during the study
8. Known pregnancy or lactation during the study period
9. 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
10. Participation in any clinical trial within 30 days of the enrollment visit

Date of first enrolment
01/07/2018

Date of final enrolment
30/10/2018

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			15/04/2020	No	No
HRA research summary			28/06/2023	No	No

Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes