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Observation of patients with dry eyes treated with HYLO NIGHT® eye ointment

Submission date
18/08/2022

Recruitment status
No longer recruiting

Registration date
23/08/2022

Overall study status
Completed

Last Edited
03/12/2024

Condition category
Eye Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
The aim of this study is to investigate the safety and performance of HYLO NIGHT® eye ointment in the treatment of dry eye symptoms. Patients suffering from dry eyes report bothersome symptoms which can even lead to impaired quality of life. Dry eye symptoms depend on the severity of the illness and are described by affected persons for example as a foreign body sensation, eyes burning, tired eyes or itching eyes. Dry eye disease is caused by either a lack in tear film volume or an increase in evaporation of the tear film, and very often a combination of both forms occurs. Dry eye disease can be treated by applying lubricating eye drops (usually as therapy during the day) and eye ointments (usually as night therapy), which serve to relieve symptoms and help to improve the quality of the tear film. Eye care by applying eye drops and/or eye ointments is therefore one of the main pillars in the treatment of dry eye disease. In total, 40 patients in two study centres (20 patients at each centre) are included in this study. Tear film quality is analysed by standard investigation of the eye, which includes the measurement of the non-invasive tear break-up time (NIBUT), the assessment of the corneal surface (the outer dome of the eye), eyelid margins and conjunctiva (covering the front surface of the eye and the inner surface of the eyelids). Beyond these parameters all patients will describe their discomfort using questionnaires. The doctor and the patient will evaluate the tolerance of the eye drops. The effectiveness is also rated by the doctor. Visual acuity (clarity of vision), intraocular (eye fluid) pressure and corneal sensitivity are also investigated.

Who can participate?
Patients suffering from dry eye symptoms and aged older than 18 years are asked about the clinical examination during the routine examination. If they are interested, they are informed about the clinical study. The patients are only recruited and treated in the study centres participating in the clinical trial. Since pregnancy or breastfeeding involves a substantial change in tears due to the hormonal change, pregnant women and breastfeeding women are excluded from the study. Further, patients with specific medical (pre)conditions or undergoing pharmacological (ocular) treatment might not be suitable for participating in this study.

What does the study involve?
The study encompasses only routine eye investigations to diagnose dry eye disease. The patients will visit the doctor up to four times during the study. The investigations include the

measurement of non-invasive tear film break-up time (NIBUT). The cornea, eyelids and conjunctiva are investigated with a special microscope (called a slit lamp). Subjective discomfort is recorded using questionnaires. All patients are treated with HYLO NIGHT® eye ointment.
If the patient uses lubricating eye drops during the day, he/she can switch to a product recommended by the doctor, if necessary, within the scope of participating in this study. If the patient decides to change the daily therapy, the changeover phase will last 2 weeks. As a result, the patient has a total of four examination appointments instead of three and the duration of the study is extended by 2 weeks due to the conversion phase from 4 weeks to 6 weeks.
The examinations are carried out at up to four visits (day 0 [screening], day 1 [baseline], day 7±2 and day 28±3). The need for therapy with HYLO NIGHT® eye ointment is determined on day 0 (screening) or day 1 (baseline), by the treating doctor and the therapy is carried out and monitored according to the doctor´s instructions. The dosage and application of the investigational product HYLO NIGHT® eye ointment is once per day before going to bed. In total, each patient will use the product for 4 weeks. The patient will assess the tolerance of the product on the follow-up visit (day 7±2) and the final visit (day 28±3). As part of the final visit (day 28±3), the attending doctor assesses whether the use of HYLO NIGHT® eye ointment has shown the desired effect and was well tolerated. The study ends with the last examination of the last patient.

What are the possible benefits and risks of participating?
The use of eye ointments in addition to lubricating eye drops is one of the main pillars in the treatment of dry eye symptoms as patients usually have a high level of suffering and impaired life quality. Application of eye ointments may lead to a significant improvement in symptom severity. Participants in this study benefit from close support from the doctor during the study period.
Treatment with HYLO NIGHT® eye ointment can lead to side effects or unwanted symptoms. With the application of HYLO NIGHT® eye ointment, mild irritation of the eyes is possible. In some cases, hypersensitive reactions might occur, which usually end immediately when the use is discontinued. Temporary blurred vision is likely after application due to the viscosity of the ointment. As with any preparation, new, previously unknown side effects can occur when using HYLO NIGHT® eye ointment. In addition, the measures taken as part of this clinical trial can lead to symptoms (e.g. irritation of the eye) or might involve risks (e.g. allergy to a preparation required for diagnostics).
HYLO NIGHT® eye ointment is a certified medical device for the treatment of dry eye symptoms containing well-known substances to treat the given symptom. Based on the existing clinical experience with this product, no serious unwanted events or unwanted long-term effects are expected for the treatment with HYLO NIGHT® eye ointment.

Where is the study run from?
URSAPHARM Arzneimittel GmbH (Germany)

When is the study starting and how long is it expected to run for?
August 2021 to December 2023

Who is funding the study?
URSAPHARM Arzneimittel GmbH (Germany)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title
Observation of sicca patients treated with HYLO NIGHT® eye ointment

Acronym
NIGHT-DRY

Study objectives
Observation of the effectiveness and tolerability of HYLO NIGHT® eye ointment in patients with dry eyes. Particular attention is paid to the non-invasive tear break up time (NIBUT).

Ethics approval required
Old ethics approval format

Ethics approval(s)

1. Approved 14/07/2022, Ethics Committee of the State Medical Association of Thuringia (lm Semmicht 33, 07751 Jena, Germany; + 49 (0) 3641614-0; ethikkommission@Iaek-thueringen.de), ref: 75099/2022/66
2. Approved 08/08/2022, Ethics Committee of the North Rhine Medical Association (Tersteegenstr. 9, 40474 Düsseldorf, Germany; +49 (0)211 4302 2272; ethik@aekno.de), ref: 2022175

Primary study design
Observational

Study design
Multicenter prospective open-label clinical trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Dry eye disease

Interventions
Screening comprises 40 patients (40 eyes) with dry eye disease. HYLO NIGHT® eye ointment serves as the investigational product and is applied into the conjunctival sac once a day before going to bed. In total, each patient will use the product for 4 weeks.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
HYLO NIGHT®

Primary outcome(s)
Non-invasive Tear Break Up Time (NIBUT) measured using a keratograph at baseline and day 28±3

Key secondary outcome(s)
1. Subjective complaints assessed with questionnaire (visual analogue score [VAS], Ocular Surface Disease Index [OSDI]) at baseline, day 7±2 and day 28±3
2. Visual acuity measured by line read in decimal numbers with correction at baseline, day 7±2 and day 28±3
3. Conjunctiva (conjunctival hyperemia, lid-parallel conjunctival folds [LIPCOF], conjunctival staining with lissamine greenand) examined using slit lamp at baseline, day 7±2 and day 28±3
4. Staining of the cornea with fluorescein examined using a slit lamp at baseline, day 7±2 and day 28±3
5. Eyelid margins examined using slit lamp at baseline, day 7±2 and day 28±3
6. Intraocular pressure measured using non-contact tonometry at baseline
7. Corneal sensitivity measured using an esthesiometer at baseline
8. Tolerability assessed by questioning the patient on day 7±2 and day 28±3
9. Effectiveness and tolerability assessed by questioning the investigator on day 28±3

Completion date
19/12/2023

Eligibility

Key inclusion criteria
1. Male and female patients, at least 18 years of age
2. Patients with binocular moderate dry eyes, defined as follows:
2.1. Non-invasive tear breakup time (NIBUT) ≤9 sec
2.2. Ocular surface staining grade is between ≥4 and ≤ 9 on the 15-point Oxford Grading Scale
3. Subjective complaints in terms of a moderately dry eye (frequency, severity, foreign body sensation, dryness, burning, tearing, tired eyes) for at least 3 months:
3.1. VAS ≥3/10 (each for frequency, severity)
3.2. OSDI ≥15
4. Corneal sensitivity ≥5
5. Stable therapy (systemic) ≥4 weeks
6. Patient's ability to provide consent
7. The patient is able and willing to meet the requirements of the protocol

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
44

Key exclusion criteria
1. Dry eye caused by systemic disease, concomitant pharmacological therapy, or malignancy
2. Other therapeutic interventions at the discretion of the investigator, e.g. mechanical cleaning of the eyelid margins, LipiflowTM, IPL. Maskin probing, administration of tear substitutes containing lipids, water-free or containing preservatives
3. Ocular surgeries within the last 3 months
4. Lid misalignment and/or lagophthalmos
5. Use of punctum plugs within the last 3 months
6. Contact lens wearers
7. Use of other pharmacological ophthalmic drugs within the last 4 weeks
8. Hypersensitivity to any of the ingredients
9. The patient is a pregnant or breastfeeding woman
10. The patient is a woman of childbearing potential without regular and correct use of a

contraceptive method with a failure rate <1% (e.g., sexual abstinence, estrogen- and progestin-containing contraceptives, vasectomy, intrauterine device (IUD) with hormones)
11. Simultaneous participation in a clinical trial or another clinical trial within the last 4 weeks
12. Previous participation in this clinical investigation or the patient is the investigator himself or a member of the staff involved in the clinical investigation
13. Inability to understand the language and/or content of the written patient information

Date of first enrolment
16/09/2022

Date of final enrolment
21/11/2023

Locations

Countries of recruitment
Germany

Study participating centre
REGIOMED Rehaklinik Masserberg
Hauptstraße 18
Masserberg
Germany
98666

Study participating centre
AugenCentrum Erkelenz
Ostpromenade 41
Erkelenz
Germany
41812

Sponsor information

Organisation
URSAPHARM (Germany)

ROR
https://ror.org/031t42b47

Funder(s)

Funder type
Industry

Funder Name
URSAPHARM Arzneimittel GmbH

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