ISRCTN32174563 https://doi.org/10.1186/ISRCTN32174563

HYLO DUAL INTENSE® versus THEALOZ DUO GEL eye drops in the treatment of patients with dry eye symptoms

Submission date 02/11/2021	**Recruitment status** No longer recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 08/11/2021	**Overall study status** Completed	
Last Edited 03/12/2024	**Condition category** Eye Diseases	

Plain English summary of protocol

Background and study aims

The aim of this study is to compare the safety and performance of two different moisturizing eye drops, namely HYLO DUAL INTENSE®or THEALOZ DUO GEL eye drops in the treatment of dry eye symptoms, which can be bothersome, or 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 and moisturizing eye drops, which serve to relieve symptoms and help to improve the quality of the tear film. Tear substitution is therefore one of the main pillars in the treatment of dry eye disease. In total, 60 patients are included with 30 patients assigned to each treatment group (either HYLO DUAL INTENSE®or THEALOZ DUO GEL). Tear film quality is analysed by standard investigation of the eye, which includes the measurement of the non-invasive tear film break-up time, the assessment of the corneal (eye) surface, eyelid margins and conjunctiva, as well as the lipid-layer-thickness (LLT, meaning the thickness of the outer layer of the tear film). Beyond these parameters all patients will describe their subjective discomfort. Further, the physician will evaluate the tolerance and effectiveness of the eye drops. In addition, visual acuity and intraocular (eye fluid) pressure are investigated.

Who can participate?

Patients with dry eye symptoms and aged older than 18 years

What does the study involve?

The study encompasses only routine eye tests to diagnose dry eye disease. The patients will visit the investigator three times during the study. The investigations include the measurement of non-invasive tear film break-up time (NIBUT) and the lipid-layer thickness (LLT). The cornea, eyelid and conjunctiva are investigated with a special microscope (called a slit lamp). Subjective discomfort is recorded using a questionnaire. All patients are randomly assigned to one treatment group (HYLO DUAL INTENSE®or THEALOZ DUO GEL). The patient does know which product he/she receives. The tests are carried out at three visits (day 1, day 28±3 and day 56±4).

The need for treatment with HYLO DUAL INTENSE®/ THEALOZ DUO GEL eye drops is determined at day 1 by the treating physician and is carried out and monitored according to the investigator´s instructions. The dosage applied is 3 x 1 per day. In total, each patient will use the product for at least 12 weeks. The patient will assess the tolerance of the product on the second (day 28±3) and third (day 56±4) visit. As part of the third visit (day 56±4), the attending physician assesses whether the use of HYLO DUAL INTENSE®/ THEALOZ DUO GEL eye drops 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 lubrication substances 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 lubricating and moisturising eye drops may lead to a significant improvement of symptom severity. Participants in this study benefit from the close support by the investigator during the study period.
Treatment with HYLO DUAL INTENSE®or THEALOZ DUO GEL eye drops can lead to side effects or unwanted symptoms. With the application of HYLO DUAL INTENSE®or THEALOZ DUO GEL eye drops, mild irritation of the eyes is possible. In some cases, hypersensitive reactions might occur, which usually stopped immediately when the use is discontinued. Temporary blurred vision is possible after application due to the viscosity of the eye drops. As with any preparation, new previously unknown side effects can occur when using HYLO DUAL INTENSE®or THEALOZ DUO GEL eye drops. 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 DUAL INTENSE®and THEALOZ DUO GEL eye drops are both certified medical devices for the treatment of dry eye symptoms. Both products contain well-known substances to treat the given symptom. Based on the existing clinical experience with these product classes, no serious unwanted events or unwanted long-term effects are expected for the treatment with HYLO DUAL INTENSE®and THEALOZ DUO GEL eye drops.

Where is the study run from?
URSAPHARM (Germany)

When is the study starting and how long is it expected to run for?
June 2020 to April 2023

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

Who is the main contact?
Dorothea Gross
d.gross@ursapharm.de

Contact information

Type(s)
Scientific

Contact name
Mrs Dorothea Groß

Contact details
Industriestrasse 35
Saarbrücken
Germany
66129
+49 (0)68059292132
d.gross@ursapharm.de

Type(s)
Scientific

Contact name
Mr Stefan Schorr

Contact details
Industriestrasse 35
Saarbrücken
Germany
66129
-
stefan.schorr@ursapharm.de

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
HYLO DUAL INTENSE® versus THEALOZ DUO GEL eye drops in the treatment of patients with dry eye symptoms: a randomized, blinded, non-inferiority study

Acronym
KÄLL01

Study objectives
The study aims to compare the efficacy and tolerability of HYLO DUAL INTENSE® and THEALOZ DUO GEL eye drops in the treatment of patients with moderate to severe dry eye symptoms. Particular attention is paid to the non-invasive tear-film break-up time (NIBUT).

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 13/10/2021, Swedish Ethical Review Authority (Etikprövningsmyndigheten, Box 2110, 750 02 Uppsala, Sweden; +46 (0)10-475 08 00; registrator@etikprovning.se), ref: Dnr 2021-05345-01

Study design
Randomized single-blind monocentric prospective clinical study

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Screening comprises 60 patients with moderate to severe dry eye disease (30 patients per group). The groups formed are:
Group 1: HYLO DUAL INTENSE®, 3 x 1 drop per day
Group 2: THEALOZ DUO GEL, 3 x 1 drop per day
The eye drops are applied into the conjunctival sac of the patient.
Randomisation numbers are calculated using block randomisation for sequence generation. A randomisation list is created by an independent person. Due to the single-blind set-up, it is not evident to the investigator whether HYLO DUAL INTENSE® or THEALOZ DUO GEL is applied. Emergency envelopes (code breakers) are prepared for urgent unblinding.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
HYLO DUAL INTENSE® THEALOZ DUO GEL

Primary outcome(s)
Non-invasive Tear Break Up Time (NIBUT) measured using a Scheimpflug camera at day 1 and day 28±3

Key secondary outcome(s))
1. Examination of eyelid margins using a slit lamp at day 1, day 28±3 and day 56±4
2. Examination of the conjunctiva (hyperaemia and after vital staining) using a slit lamp at day 1, day 28±3 and day 56±4
3. Examination of the cornea after vital staining using a slit lamp at day 1, day 28±3 and day 56±4
4. Thickness of lipid layer (LLT) measured with the Kowa DR-1 α Dry Eye Monitor at day 1, day 28±3 and day 56±4
5. Subjective discomfort feeling measured using the Ocular Surface Disease Index at day 1, day 28±3 and day 56±4
6. Intraocular pressure (IOP) measured using a Huvitz non-contact tonometer at day 1, day 28±3

and day 56±4
7. Visual acuity measured in decimal numbers by line read with correction at day 1, day 28±3 and day 56±4
8. Tolerability evaluated by questioning the patient at day 28±3 and day 56±4
9. Efficacy assessed by questioning the investigator at day 56±4
10. Tolerability assessed by questioning the investigator at day 56±4
11. Frequency and number of investigational product-related adverse, and serious adverse events by questioning at day 28±3 and day 56±4
12. Non-invasive tear break up time (NIBUT) measured using a Scheimpflug camera at day 1, 28±3 and 56±4

Completion date
30/03/2023

Eligibility

Key inclusion criteria
1. Male and female patients ≥18 years of age
2. Patients with binocular moderate to severe dry eyes since at least 3 month and defined as:
2.1. Non-invasive tear-film breakup time (NIBUT) ≤5 sec
2.2. Degree of staining of the eye surface is between ≥3 and ≤9 on the Oxford Grading Scale with 15 points
3. Subjective complaints in the sense of a moderate to severe dry eye since at least 3 months: OSDI© ≥23
4. Ability of the patient to provide informed consent
5. The patient is able and ready 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
76

Key exclusion criteria
1. Change of therapeutic (pharmacological) ophthalmic or systemic agents and dosage within the last 3 months and during the course of the study
2. Ocular operations within the last 3 months
3. Eyelid misalignment and/or lagophthalmos

4. Use of punctum plugs within the last 3 months
5. Contact lens wearers
6. Hypersensitivity to any of the ingredients
7. The patient is pregnant or breastfeeding
8. The patient is a woman of childbearing age without regular and correct use of a contraceptive method with an error rate of <1% (e.g. sexual abstinence, contraceptives containing estrogen and gestagen, vasectomy, intrauterine device with hormones)
9. Simultaneous participation in a clinical trial or in another clinical trial within the last 4 weeks
10. Previous participation in this study or the patient is the investigator or a member of the staff involved in the study
11. Inability to understand the written patient information linguistically and/or in terms of content

Date of first enrolment
12/01/2022

Date of final enrolment
31/12/2022

Locations

Countries of recruitment
Sweden

Study participating centre
Källmarkskliniken AB
Vretenvägen 8
Solna
Sweden
171 54

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
Participant level data is not to be made available for company policy reasons. Data are kept at the study centre of Dr Källmark.

IPD sharing plan summary
Not expected to be made available