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Assessing the effectiveness of a tear substitute with ST-Lysyal in managing symptoms and eye surface changes in people with dry eye disease

Submission date
08/05/2023

Recruitment status
No longer recruiting

Registration date
09/05/2023

Overall study status
Completed

Last Edited
20/11/2024

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
Dry eye is a condition where your eyes don't have enough moisture or lubrication to stay comfortable and healthy. It can happen when your tears evaporate too quickly or when your eyes don't produce enough tears. This can cause symptoms like dryness, redness, irritation, and a feeling of grittiness in your eyes.
This study aims to test the effectiveness of new tear substitutes that are part of a group of substances called "ocular surface modulators." These substitutes are designed to help improve the symptoms and signs associated with dry eye.

Who can participate?
Adult patients with dry eye.

What does the study involve?
Participants will be randomly allocated to use either Relys eye drops or Xiloial Zero eye drops three times per day for two months.

What are the possible benefits and risks of participating?
Patients will undergo treatment for dry eye disease with a tear substitute that has been demonstrated to be effective in pre-clinical studies. Patients suffering from symptoms of dry eye may have beneficial effects from this treatment. The tear substitute used in the study have been on the market for some years and no side effects have been reported.

Where is the study run from?
Ocular surface and Dry Eye Center at the Sacco Hospital in Milan (Italy)

When is the study starting and how long is it expected to run for?
September 2022 to December 2023

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Stefano Barabino, stefano.barabino@asst-fbf-sacco.it

Contact information

Type(s)
Principal investigator

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Additional identifiers

Protocol serial number
2022/ST/165

Study information

Scientific Title
Evaluation of the performance of a tear containing ST-Lysyal in controlling symptoms and ocular surface changes in patients with dry eye disease

Study objectives
The intent of this clinical study is to evaluate the performance of eye drops containing ST-LYS versus a tear substitute containing 0.4% hyaluronic acid over two months by studying symptoms, tear film stability, and corneal epithelial damage in patients with dry eye disease

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/12/2022, Ethics Committee Milano Area 1 of the Sacco Hospital (via G.B. Grassi 74, Milan, Italy; +39-02 39043518; comitato.etico@asst-fbf-sacco.it), ref: 2022/ST/165

Primary study design
Interventional

Study design

Monocenter randomized controlled double-blinded interventional study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Treatment of dry eye disease

Interventions
Patients will be divided into two groups and treatments will be assigned following a randomization list. The study group will use Relys eye drops and the control group Xiloial Zero.

The randomisation process is by sealed envelope.

Patients will use one drop of each treatment that will be instilled 3 times/day for two months.

Intervention Type
Device

Phase
Phase III/IV

Drug/device/biological/vaccine name(s)
Relys collirio; Xiloial Zero collirio

Primary outcome(s)
Symptoms are measured using SANDE questionnaire at baseline, 4 and 12 weeks

Key secondary outcome(s)
1.Corneal fluorescein staining (score 0-15) measured after instilling fluorescein on the ocular surface at baseline, 4 and 12 weeks
2. Tear break-up time (seconds) measured after instilling fluorescein on the ocular surface at baseline, 4 and 12 weeks

Completion date
31/12/2023

Eligibility

Key inclusion criteria
1. Patients of both sexes affected by dry eye disease with persistent/intermittent symptoms for at least 6 months
2. SANDE questionnaire score at baseline ≥ 30 and simultaneous positivity to at least one of the following parameters:
3. Corneal fluorescein staining score ≥ 2 (NEI National eye Institute grading scale)
4. Average T-BUT (Tear Film Break up Time) ≤ 10 seconds
5. Ability to provide written informed consent and follow study procedures
6. Women of childbearing potential who are negative for a pregnancy test

Participant type(s)

Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Patients in systemic and/or local therapy with products with anti-inflammatory activity
2. Patients with other ocular surface pathologies in progress
3. Surgical or parasurgical interventions in the study eye within 3 months prior to the start of treatment
4. Pregnancy or breastfeeding

Date of first enrolment
10/05/2023

Date of final enrolment
30/09/2023

Locations

Countries of recruitment
Italy

Study participating centre
Ospedale L. Sacco
via G.B. Grassi 74
Milan
Italy
20157

Sponsor information

Organisation
Ospedale L. Sacco

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as supplement to the results publication

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		19/11/2024	20/11/2024	Yes	No