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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

### Contact name
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# Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
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

## Study design
Monocenter randomized controlled double-blinded interventional study

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

## 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 measure
Symptoms are measured using SANDE questionnaire at baseline, 4 and 12 weeks

## Secondary outcome measures

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

### Overall study start date
01/09/2022

### 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

### Age group
Adult

### Sex
Both

### Target number of participants
30

### 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**
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## Sponsor information

### Organisation
Ospedale L. Sacco

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### Sponsor type
Hospital/treatment centre

### Website
https://www.asst-fbf-sacco.it

## Funder(s)

### Funder type
Other

### Funder Name
Investigator initiated and funded

## Results and Publications

### Publication and dissemination plan

Planned publication in a high-impact-peer reviewed journal

## Intention to publish date
01/05/2024

## 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 |