

Evaluation of the performance of new substitute tears in dry eye patients

Submission date 28/07/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 05/08/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 20/06/2023	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Dry eye disease (when the eyes do not make enough tears, or the tears evaporate too quickly) is very common and affects millions of people around the world.

The aim of the study is verify the efficacy of a substitute tear containing 0.001% hydrocortisone to improve symptoms and inflammation in dry eye patients.

Who can participate?

Patients older than 18 years who have suffered from dry eye symptoms for at least 6 months

What does the study involve?

Participants will be randomly allocated to receive eye drops with or without 0.001% hydrocortisone. These will be used twice daily for one week to check for any problems. After the first week the drops will be used 4 times a day for 6 months. Participants will visit the clinic to be tested on day 7, 28, 56, 180.

What are the possible benefits and risks of participating?

The product used in the study has not demonstrated any side effects so far.

Where is the study run from?

Ocular Surface and Dry Eye Center, Sacco Hospital, Milan (Italy)

When is the study starting and how long is it expected to run for?

March 2019 to April 2021

Who is funding the study?

Investigator initiated and funded

Who is the main contact?

Stefano Barabino, MD, PhD, at stefano.barabino@unimi.it

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers**Protocol serial number**

2019/ST/048

Study information**Scientific Title**

Evaluation of the performance of a substitute tear containing hyaluronic acid and a low concentration of hydrocortisone to control ocular surface inflammation and symptoms in patients with dry eye disease

Study objectives

Substitute tear containing hyaluronic acid and low concentration of hydrocortisone improves symptoms and signs of dry eye disease

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 19/9/2019 Milan Area 1 Ethic Committee (Luigi Sacco hospital, via G.B. Grasi 74, Milan, Italy; +39 0239043518; comitato.etico@asst-fbf-sacco.it), ref: 39408/2019

Study design

Interventional double masked randomized study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Dry eye disease

Interventions

Patients are randomized in study and control group using a pre-defined list. All patients will use topical steroid Fluorometholone twice daily and treatment (HA + 0.001% hydrocortisone) or control (HA alone) eye drops twice daily for one week. At the end of the first week, patients will keep using eye drops 4 times a day for 6 months

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

1. Fluorometholone 2. HA + 0.001% hydrocortisone

Primary outcome(s)

Symptom improvement measured by SANDE score at day 7, 28, 56, 180

Key secondary outcome(s)

1. Corneal fluorescein staining, NEI scale, at day 7, 28, 56, 180
2. Lissamine green conjunctival staining, NEI scale, at day 7, 28, 56, 180
3. Tear break-up time (BUT), seconds, at day 7, 28, 56, 180
4. Intraocular pressure (IOP), mmHg, at day 7, 28, 56, 180

Completion date

10/04/2021

Eligibility

Key inclusion criteria

1. Dry eye symptoms for at least 6 months, and one of the following signs:
 - 1.1. Corneal fluorescein staining ≥ 3 (NEI National eye Institute grading scale)
 - 1.2. Conjunctival lissamine green staining ≥ 3 (NEI National eye Institute grading scale)
 - 1.3. T BUT (Tear Film Break up Time) ≤ 10 s

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

40

Key exclusion criteria

1. Patients changing systemic treatment during the study
2. Patients with other ocular surface diseases other than dry eye
3. Pregnancy
4. Diabetes
5. Ocular surgery in the previous 3 months

Date of first enrolment

10/06/2020

Date of final enrolment

10/04/2021

Locations**Countries of recruitment**

Italy

Study participating centre

Ospedale L. Sacco-University of Milan

Clinica Oculistica

via GB Grassi 74

Milan

Italy

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Sponsor information**Organisation**

Luigi Sacco Hospital

ROR

<https://ror.org/0025g8755>

Funder(s)**Funder type**

Other

Funder Name

investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		19/06/2023	20/06/2023	Yes	No