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

Submission date	Recruitment status	[_] Prospectively registered
28/07/2020	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
05/08/2020	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
20/06/2023	Eye Diseases	

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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Secondary outcome measures
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

Overall study start date
07/03/2019

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

Age group
Adult

Sex
Both

Target number of participants
40

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
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Sponsor information

Organisation
Luigi Sacco Hospital

Sponsor details
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Sponsor type
Hospital/treatment centre

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

ROR
https://ror.org/0025g8755

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
01/06/2021

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