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Evaluation of the efficacy of a food supplement in reducing dry eye symptoms

Submission date	Recruitment status	[_] Prospectively registered
13/11/2026	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/11/2026	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
16/11/2026	Eye Diseases	[X] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

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Additional identifiers

Clinical study protocol
NT0000234-25

Study information

Scientific Title
Clinical evaluation of the efficacy of a food supplement in reducing dry eye symptoms: a randomized, double-blind, parallel-group, placebo-controlled study

Study objectives

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 16/05/2025, Independent Ethics Committee for Non-Pharmacological Clinical Investigations (Italian Scientific Society for Non-Pharmacological Clinical Investigations Via XX Settembre 30/4, Genova, 16121, Italy; +39 (0)10 5454842; a.scudieri@studinonfarmacologici.it), ref: 2025/10

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Parallel

Purpose
Treatment, Efficacy

Study type(s)

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

Interventions
The study will be a double-blind, randomized, parallel-group, placebo-controlled clinical study. Half of the subjects will take the active product EXCEPTIONHYAL® WINK containing sodium

hyaluronate and half of the subjects will take a placebo for 56 days (T0 to T56). A restricted randomization list will be generated by an independent technician using the appropriate algorithm ("Wei's urn") of the PASS 11 software (PASS, LLC, Kaysville, UT, USA) and stored in a secure location. The principal investigator or his delegate will dispense the products according to the generated randomization list. Subjects will take one capsule a day in the morning, on an empty stomach, with a glass of water.

Intervention Type
Supplement

Primary outcome(s)
1. Tear production Schirmer test I measured using the Schirmer test I at T0, T56

2. Tear film stability measured using the Fluorescein Tear Breakup Time (TBUT) test at T0, T56

3. Conjunctival hyperemia measured using slit lamp, and the physical sign will be assessed using a 5- point scoring system, where 0 corresponds to no signs, 1 to very mild, 2 to mild, 3 to moderate, and 4 to severe. Conjunctival hyperemia is characterized by increased redness of the eye caused by the dilation of blood vessels in the conjunctiva at T0, T56

4. Dry eye symptoms and their impact on vision-related function over the past week measured using the Ocular Surface Disease Index (ODSI) at T0, T28, T56

5. Subjective dry eye symptoms and their impact on daily activities over the past week measured using the Dry Eye-Related Quality-of-Life Score (DEQS) at T0, T28, T56

Key secondary outcome(s)

Completion date
26/09/2025

Eligibility

Key inclusion criteria
1. Healthy male and female subjects
2. Caucasian ethnicity
3. Subjects aged between 18 and 64 years (extremes included)
4. Subjects suffering from dry eye discomfort*
5. 34 subjects wear contact lenses, while 32 subjects wear glasses or have normal vision and do not need glasses or contact lenses
6. Subjects registered with National Health Service (NHS)
7. Subjects certifying the truthfulness of the personal data disclosed to the investigator
8. Subjects able to understand the language used in the investigation center and the information given by the investigator
9. Subjects able to respect the instructions given by the investigator as well as able to respect the study constraints and specific requirements
10. Commitment not to change the daily routine or the lifestyle
11. Stable pharmacological therapy (except for the pharmacological therapy in the non-inclusion criteria) for at least 1 month without any changes expected or planned during the study
12. Subjects informed about the test procedures who have signed a consent form and privacy agreement

*At T0 Ocular Surface Disease Index (ODSI) between 13 and 32 and Dry Eye Questionnaire 5 (DEQ-5) between 6 and
12.
ODSI: is a 12-item questionnaire to assess dry eye symptoms and their impact on vision-related function over the past week. It consists of three subscales: ocular symptoms, vision-related function, and environmental triggers.
Subjects rate each item on a scale from 0 to 4. Based on the total score, symptoms are classified as follows: normal (0–12), mild dry eye (13–22), moderate dry eye (23–32), severe dry eye (33–100).
DEQ-5: is a 5-item questionnaire assessing symptoms experienced in the past month. It evaluates frequency of watery eye, discomfort, and dryness (scored on a 0–4 scale) and intensity of late-day discomfort and dryness (scored on a 0–5 scale). A total score greater than 6 indicates the presence of dry eye, while a score greater than 12 may require further investigation to exclude the possibility of Sjögren's syndrome.

Healthy volunteers allowed
Yes

Age group
Adult

Lower age limit
18 Years

Upper age limit
64 Years

Sex
All

Total final enrolment
66

Key exclusion criteria
1. Subjects who do not meet the inclusion criteria
2. Subjects wearing glasses with blue light-blocking lenses
3. Subjects with any acute, chronic, or progressive disease or condition that may interfere with the study data or that the investigator considers dangerous to the subject or incompatible with the requirements of the study
4. Subjects participating or planning to participate in other clinical trials
5. Subjects who participated in a similar study without respecting an adequate washout period (at least 1 month)
6. Subjects that have food intolerances or food allergies to ingredients of the study product
7. Subjects under pharmacological treatments that are considered incompatible with the study requirement by the investigator*
8. Subjects who are currently using food supplement(s) and/or topical products (i.e. eye drops) with the same activity as the study product, or who haven't observed an adequate washout period (at least 1 month)**
9. Subjects admitted to a health or social facility
10. Subjects planning a hospitalization during the study
11. Subjects not able to be contacted in case of emergency

12. Subjects deprived of freedom by administrative or legal decision or under guardianship
13. Subjects with a history of drug, alcohol and other substance abuse
14. Subjects with eating disorders (i.e. bulimia, psychogenic eating disorders, etc)
15. Subject breastfeeding, pregnant or not willing to take necessary precautions to avoid pregnancy during the study (for the women of childbearing potential)
*Systemic medications that stimulate tear secretion (e.g., pilocarpine, cevimeline)
**Topical ophthalmic medications (corticosteroids, NSAIDs, and cyclosporine); supplements containing omega-3,
vitamin A, vitamin E, lutein, zeaxanthin, and lactoferrin

Date of first enrolment
16/05/2025

Date of final enrolment
28/05/2025

Locations

Countries of recruitment
Italy

Study participating centre
Nutratech SRL
Via Francesco Todaro 20/22
Rende
Italy
87036

Sponsor information

Organisation
ROELMI HPC SRL (Italy)

ROR
https://ror.org/01z3gay43

Funder(s)

Funder type

Funder Name
ROELMI Srl

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available