ISRCTN15276264 https://doi.org/10.1186/ISRCTN15276264

Randomized comparison between two dry eye treatments

Submission date	Recruitment status	[_] Prospectively registered
17/03/2022	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/03/2022	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
22/04/2024	Eye Diseases	

Plain English summary of protocol

Background and study aims
Ocular dryness is most commonly associated with dysfunction of the meibomian glands which produce tears in your eyes. Research has pointed to the use of eye drops containing artificial tears as an effective method of treating ocular dryness associated with meibomian gland dysfunction. The aim of this study is to evaluate two types of eye lubricants (eyedrops) containing lipids (artificial tears) with one another in terms of their efficacy and safety.

Who can participate?
Adults that suffer from ocular dryness that meet all of the inclusion and none of the exclusion criteria at visits 1 and 2.

What does the study involve?
The study involves attending a clinic on four occasions and using the study product for a period of approximately three months. After one month (visit 3) and three months (visit 4) you will attend for some follow-up measurements. The measurements are routine measurements and will be carried out by an experienced clinician.

What are the possible benefits and risks of participating?
The benefits are that one may find an improvement in their ocular dryness as a result of using the study product.
The risks associated with participating are considered extremely minimal. Risks can arise when the instructions of the investigator and not followed.

Where is the study run from?
The study is being run in the UK from Ocular Technology Group - International based in central London.

When is the study starting and how long is it expected to run for?
January 2021 to May 2023

Who is funding the study?
Eurofins (France)

Who is the main contact?
Deborah Moore, dmoore@otg.co.uk

Contact information

Type(s)
Public

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Additional identifiers

Integrated Research Application System (IRAS)
309011

Protocol serial number
21E1007

Study information

Scientific Title
Multicentric, randomized, comparative clinical study on the evaluation of the efficacy and safety of Neovis® Total Multi versus Systane® Balance on the treatment of ocular dryness associated with meibomian gland dysfunction

Study objectives
Non-inferiority of Neovis® Total Multi in comparison with Systane® Balance, in terms of tear film Break-Up Time (TBUT) after 28 days of treatment on worse eye, with a limit of non-inferiority equal to 0.9 seconds.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/02/2022, London - Riverside Research Ethics Committee (Ground Floor, Temple Quay House, 2 The Square, Bristol, BS1 6PN, UK; +44 (0)207 1048184; riverside.rec@hra.nhs.uk), ref: 21/PR/1697

Primary study design
Interventional

Study design
Multicentre comparative parallel groups investigator blinded randomised study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Ocular dryness associated with meibomian gland dysfunction

Interventions
Following a review of the inclusion and exclusion criteria by an experienced investigator, participants start the study with a 7-10 day washout period in which they cease to use any pre-existing treatment for ocular dryness and are provided with wipes (which will be used throughout the study) and some eyedrops which will be used until the following visit.

At the second visit, participants are randomised into either the test or control group by a computer generated system. The control and test products are both CE marked eye drops containing lipids. Participants will be distributed the study product (in a way such that the investigator does not become aware of the group that they have been randomised into) respective to their treatment group. Study eyedrops are to be used in the same way: one drop in each eye, four times per day.

At the third visit, approximately one month after visit 2, measurements will be taken to assess the change in ocular dryness signs and symptoms. At the final visit, approximately two months after visit 3, the same measurements will be taken to assess the change in ocular dryness signs and symptoms, all study products will be returned and the participant will be discharged from the study.

Intervention Type
Supplement

Primary outcome(s)
Ocular dryness is measured in terms of Tear film Break-Up Time (TBUT) in seconds at all four visits (baseline, and approximately 7 days, 5 weeks, 14 weeks)

Key secondary outcome(s)
1. Cornea and conjunctiva staining score (Oxford score) measuring using lissamine green staining at all four visits.
2. Meibomian gland expression measured using a rating score from 1-3 at all four visits
3. Subjective expression of dryness measured using an OSDI questionnaire at all four visits.
4. Global performance of the study product measured by the investigator and participant on a four point scale from unsatisfactory to very satisfactory at the third and fourth visits.

Completion date
01/05/2023

Eligibility

Key inclusion criteria

1. Sex: male or female.
2. Age: 18 years and more.
3. Presenting dry eye symptoms for at least 6 months.
4. OSDI (Ocular Surface Disease Index) ≥ 18
5. At least one eye eligible with:
5.1. sum of peripheral corneal and conjunctival staining ≥ 4 and ≤ 9 (Oxford 0-15 grading scheme) AND
5.2. sum of 3 measurements of Tear film Break-Up Time (TBUT) ≤ 15s
6. Meibomian Gland Dysfunction on at least one eye (same eye eligible) with a score of 1 or higher for meibum quality score (from 0: clear to 3: toothpaste/obstruction) and evidence of partial or whole missing Meibomian Glands.
7. Ability and willingness to apply eyelid hygiene during the whole study, including wash-out period.
8. Having given freely and expressly his/her informed consent.
9. Able to comply with the study requirements, as defined in the present CIP, at the Investigator' s appreciation.
10. In France: subject being affiliated to a health social security system.
11. Female subjects of childbearing potential should use a medically accepted contraceptive regimen since at least 12 weeks before the beginning of the study, during all the study and at least 1 month after the study end.

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Pregnant or nursing woman or planning a pregnancy during the study.
2. Subject deprived of freedom by administrative or legal decision.
3. Subject in a social or health institution
4. Subject who is under guardianship or who is not able to express his/her consent.
5. Use of contact lenses in either eye during the study.
6. Far best-corrected visual acuity ≤ 1/10.
7. Subject with severe ocular dryness with one of these conditions:
7.1. Eyelid or blinking malfunction
7.2. Corneal disorders not related to dry eye syndrome
7.3. Ocular metaplasia
7.4. Filamentous keratitis
7.5. Corneal neovascularization
8. History of ocular traumatism, ocular infection or ocular inflammation within the last 3 months.

9. History of ocular allergy or ocular herpes within the last 12 months.
10. Subjects who underwent ocular surgery, including laser surgery, in either eye within the last 6 months.
11. Any troubles of the ocular surface not related to dry eye syndrome.
12. Use of the following ocular treatments: isotretinoïd, cyclosporine, tacrolimus, sirolimus, pimecrolimus during the month preceding the inclusion.
13. IOP > 21 mmHg
14. Uncontrolled systemic disease
15. Alcohol abuse
16. Psychiatric disorders
17. Cognitive impairment that could affect evaluation of preferences or inability to understand written patient information
18. Participation in other clinical studies in the last month
19. Hypersensitivity to one or more components of the study product
20. Dry eye due to systemic disease, concomitant medication, malign conditions or idiopathic causes
21. Punctual plugs during the past 3 months
22. Use of lipid-containing eye drops during the past 3 months
23. Use of other therapeutic ophthalmics during the past 3 months
24. Earlier participation at this clinical trial or the patient being an investigator or a member of the personnel involved at this clinical trial

Date of first enrolment
21/03/2022

Date of final enrolment
31/12/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Ocular Technology Group - International
66 Buckingham Gate
London
United Kingdom
SW1E 6AU

Study participating centre
Vision Express Optical Lab
Eden Shopping Centre
29 Newland Street
Newlands Meadow

High Wycombe
United Kingdom
HP11 2BY

Sponsor information

Organisation
Eurofins (France)

ROR
https://ror.org/04mdycw91

Funder(s)

Funder type
Industry

Funder Name
Eurofins Viracor BioPharma

Alternative Name(s)
Eurofins Viracor BioPharma EBV, Eurofins Viracor Biopharma Services, Eurofins Viracor Biopharma Services Inc, EUROFINS VIRACOR BIOPHARMA SERVICES, INC., EVB

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan
The data in this study will belong to the sponsor and therefore it is up to the sponsor discretion whether they make the raw data available to be shared.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results	version 0.1	13/03/2024	22/04/2024	No	No
HRA research summary			28/06/2023	No	No