Summary of the Report on a Randomized, Open-label, Parallel-group, Self-controlled Human Trial of L-Ergothioneine Eye Wash for the Improving Ocular Discomfort

Research Title: A Randomized, Open-label, Parallel-group, Self-controlled Human Trial of L-Ergothioneine Eye Wash for the Improving Ocular Discomfort

Protocol Version No./Version Date: V1.0/September 24, 2024

Name of Test Product: L-Ergothioneine Eye Wash

Sponsor's Name: GeneIII Biotechnology Co., Ltd.

Principal Investigator: Jiang Jiang

Research Center: Hefei First People's Hospital

Clinical CRO: Anhui Lingka Medical Technology Co., Ltd.

Ethical Review No.: 2024- Ethical Review-28

Research Period: 2024-11-04~2024-12-03
(Date of Informed Consent Signed by the First Subject ~ Date of Completion of Follow-up of the Last Subject)

Trial Phase: IIT (Investigator Initiated Trial) Research

Research Objectives

Primary Research Objective

To study the effectiveness of L-Ergothioneine Eye Wash for the Improving Ocular Discomfort compared with self-control group.

Secondary Research Objectives

To observe the safety of L-Ergothioneine Eye Wash during the clinical trial.

Test Products

L-Ergothioneine Eye Wash 1: 5 mL (water, 0.5% ergothioneine, sodium hyaluronate, taurine, sodium chloride).

L-Ergothioneine Eye Wash 2: 0.5 mL (water, 0.5% ergothioneine, sodium hyaluronate, taurine, sodium chloride).

Research Methodology: A single-center, randomized, double-blind, parallel, placebo-controlled clinical study.

Number of Subjects

Number of subjects who completed the trial: 40 cases, with 20 cases in each Group: Test Group 1 (5 mL L-Ergothioneine Eye Wash) and Test Group 2 (0.5 mL L-Ergothioneine Eye Wash).

Test Products:

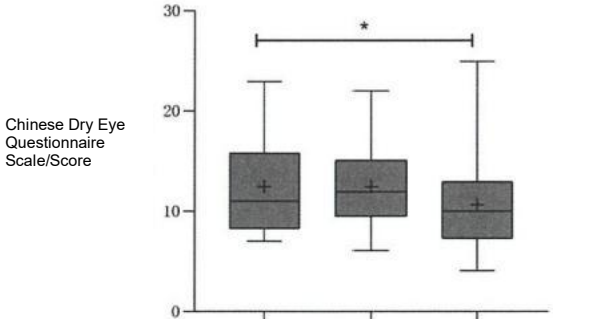
L-Ergothioneine Eye Wash 1: 5mL (water, ergothioneine 0.5%, sodium hyaluronate, taurine, sodium chloride)

L-Ergothioneine Eye Wash 2: 0.5mL (water, ergothioneine 0.5%, sodium hyaluronate, taurine, sodium chloride)

Results of Effect Evaluation Indicators:

1.Chinese Dry Eye Questionnaire Scale

The mean value of the Chinese Dry Eye Questionnaire Scale for 40 subjects at the baseline period was 12.50, and the mean value at the end-of-study period was 10.65, which decreased by 14.80%, and there was a significant difference (P = 0.0353), as shown in Figure 1.

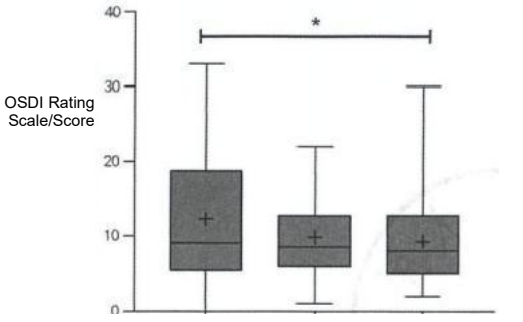


Note: * indicates $p<0.05$

Figure 1. Box Plot of the Chinese Dry Eye Questionnaire Scale

2. Ocular Surface Disease Index (OSDI) Rating Scale

The mean value of the Ocular Surface Disease Index (OSDI) score of 40 subjects at the baseline period was 12.25, the mean value at the withdrawal period was 9.23, which decreased by 24.69%, and there was a significant difference (P = 0.0309), as shown in Figure 2.

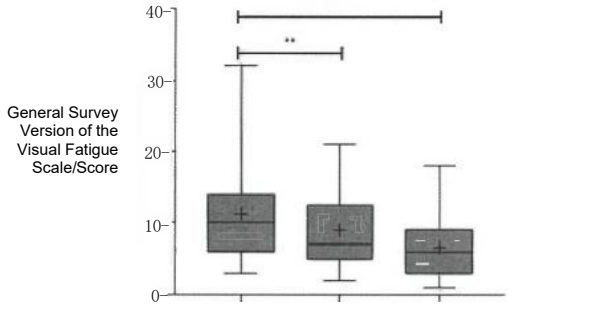


Note: * indicates p<0.05

Figure 2. Box plot of OSDI Rating Scale

3. General Survey Version of the Visual Fatigue Scale

The mean baseline value of the scores of the General Survey Version of the Visual Fatigue Scale for 40 subjects was 11.18, and the mean value at the withdrawal period was 6.60, representing a decrease of 40.94%. There was a significant difference (P = 0.0008), as shown in Figure 3.

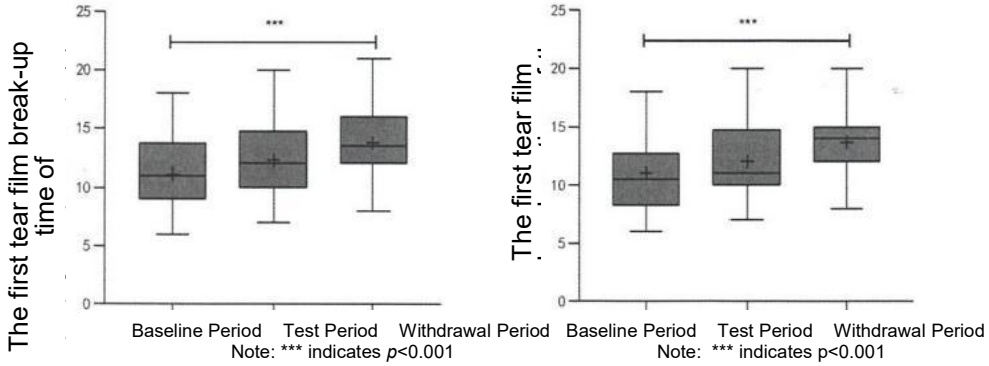


Note: ** indicates p<0.01, *** indicates p<0.001

Figure 3. Box plot for the evaluation of the General Survey Version of the Visual Fatigue Scale

4. Fluorescein Staining Tear Film Break-up Time

For the 40 subjects, at the withdrawal period, the mean values of the first tear film break-up time of the left eye, the average tear film break-up time of the left eye, the first tear film break-up time of the right eye, and the average tear film break-up time of the right eye increased by 23.60%, 24.56%, 26.98%, and 27.74% respectively compared with those at the baseline period. All of these showed statistically significant differences (P < 0.0001, P < 0.0001, P < 0.0001, P < 0.0001), as shown in Figures 4 and 5.



Note: *** indicates p<0.001 Note: *** indicates p<0.001

Figure 4 Box plot of the first (left) and average (right) tear film break-up times of the left eye

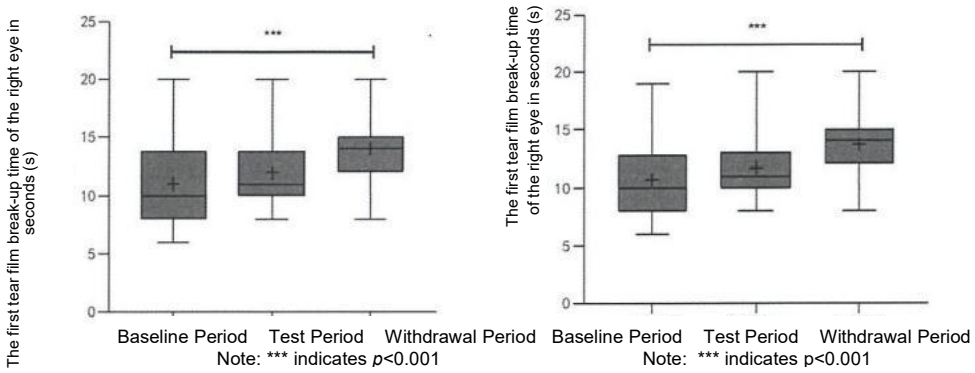


Figure 5 Box plot of the first (left) and average (right) tear film break-up times of the right eye

Results of Safety Evaluation Indicators:

A total of 40 subjects were enrolled in this trial: 20 subjects were administrated with L-Ergothioneine Eye Wash at a dosage of 5 mL per vial, while 20 subjects were administrated with L-Ergothioneine Eye Wash at a dosage of 0.5 mL per vial. All 40 subjects were included in the safety data set. No subject withdrew from the trial due to adverse events.

In the safety data set of this trial, a total of 0 subjects experienced 0 adverse events, with incidence rate of adverse events of 0%. No subject had adverse reactions or serious adverse events.

Conclusions:

Efficacy Conclusions:

Chinese Dry Eye Questionnaire Scale: After the subjects were administrated with GeneIII L-Ergothioneine Eye Wash, the mean score of the Chinese Dry Eye Questionnaire Scale in the post-treatment period was significantly lower than that in the baseline period (P = 0.0353).

Ocular Surface Disease Index (OSDI) Score: After the subjects were administrated with GeneIII L-Ergothioneine Eye Wash, the mean score of the Ocular Surface Disease Index (OSDI) in the post-treatment period was significantly lower than that in the baseline period (P = 0.0309).

General Survey Version of Visual Fatigue Scale Score: After the subjects were administrated with GeneIII L-Ergothioneine Eye Wash, the mean score of the General Survey Version of Visual Fatigue Scale in the post-treatment period was significantly lower than that in the baseline period (P = 0.0008).

Fluorescein Staining Tear Film Break-up Time: After the subjects was administrated with GeneIII L-Ergothioneine Eye Wash, the mean values of the first tear film break-up time and the average tear film break-up time of both eyes in the post-treatment period was significantly higher than those in the baseline period (P < 0.05).

Safety Conclusion:

A total of 40 subjects were included in the safety data set of this trial. No subject had adverse events. No subject had adverse reactions. No subject had serious adverse events. A comprehensive analysis of the safety results demonstrated that the L-Ergothioneine Eye Wash produced by GeneIII Biotechnology Co., Ltd. was shown with the good overall safety.