Clinical Summary Report

Evaluation of “Re:Bonel EX PREMIUM” for the Improvement of Tinea Unguium Symptoms

Conducted by the Japan Clinical Trials Association (JACTA), July 2025
Sponsor: Glorious Pharmaceutical Co., Ltd.

1. Study Objective

This study aimed to evaluate the clinical effectiveness of the quasi-drug product Re:Bonel EX PREMIUM (provided by Glorious Pharmaceutical Co., Ltd.) when applied twice daily over a period of two weeks on toenail tinea (tinea unguium) symptoms.

2. Study Design

A single-blinded, left-right comparison trial was conducted at JACTA under the supervision of Dr. Akifumi Miyata, Director of Miyata Medical Clinic. Each subject applied the test product to one foot while leaving the contralateral foot untreated, allowing intra-individual comparison. Allocation details were blinded to evaluators and securely managed until key unblinding.

3. Subjects

Participants were recruited via public advertisement through Rabbits Koko Co., Ltd. Inclusion criteria required participants to have visible symptoms of tinea unguium on both feet. A total of 17 individuals were enrolled; 16 completed the study. The mean age was 54.8 ± 7.7 years.

Key exclusion criteria included current use of antifungal medications, recent participation in other clinical studies, severe skin conditions, pregnancy or lactation, and known allergies to ingredients.

4. Ethical Considerations

The study was approved by an independent ethics committee (Chairperson: Toshio Hoga, Esq.) in accordance with the Declaration of Helsinki (October 2013, Fortaleza revision) and Japanese ethical guidelines (March 2021). Written informed consent was obtained from all participants. The study was registered under UMIN Clinical Trials Registry (ID: UMIN000058284).

5. Intervention and Product Details

The test product contained benzalkonium chloride (0.05 w/v%) as the active ingredient, along with several moisturizing and emollient agents. Subjects applied approximately 5 mm in diameter of the product to each affected toenail twice daily, ensuring coverage of the entire nail surface and surrounding area.

6. Evaluation Parameters

Primary Outcome: Subjective evaluation through a self-reported questionnaire assessing itching, odor, and nail appearance using a 5-point Likert scale.

Secondary Outcome: Image-based clinical assessment conducted by trained experts under the supervision of dermatologists, using standardized photographs pre- and post-treatment. Severity scores were graded on a 7-point scale from “marked improvement” to “marked worsening.”

Statistical analysis employed paired t-tests for subjective data and Wilcoxon signed-rank tests for image evaluations. A significance level of $p<0.05$ was considered statistically meaningful.

7. Results

Subjective Assessment: Statistically significant improvements were observed after two weeks of product use in all three categories (itching, odor, nail condition) compared to baseline ($p<0.05$), and also in comparison to the untreated foot.

Image-Based Assessment: The treated foot showed a statistically significant improvement in visual parameters (e.g., nail luster, texture, discoloration) relative to both baseline and the untreated side ($p<0.01$).

8. Conclusion

Based on both subjective self-assessments and expert image-based evaluations, Re:Bonel EX PREMIUM demonstrated clinically meaningful efficacy in improving symptoms of tinea unguium within a two-week period. These findings suggest that the product may serve as a promising non-prescription option for individuals with mild to moderate fungal nail infections.