

STUDY PROTOCOL

Title: Title: The Effectiveness of a Whitening and Anti-Aging Bilayering Serum and Cream Containing Gamma-Aminobutyric Acid (GABA) 3%, Dimethylaminoethanol (DMAE) 2%, Cysteamine 2.5%, and Bakuchiol 1%

NCT Number: NCT ID not yet assigned

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This study was experimental research with a double blind randomized controlled clinical trial design conducted at the Department of Dermatology & Venereology and Hasanuddin University Hospital, Makassar City, South Sulawesi, Indonesia, from March to August 2025. This study was approved by the Health Research Ethics Committee, Faculty of Medicine, Hasanuddin University, Makassar, with number 93/UN4.6.4.5.31/PP36/2025.

Subject

The total number of subjects was 44, female, aged between 30-50 years, and Fitzpatrick skin type III-V. All participants in the study signed an informed consent form. The exclusion criteria were pregnancy, breastfeeding, menopause, using hormonal contraception skin, being treated with topical and systemic whitening agents for 1 month before the study began, and had a history of GABA, DMAE, Bakuchiol, or Cysteamine allergic reaction.

Study Protocol

Baseline melanin index (MI), L-value, and UV spot values were measured using Mexameter®, Chromameter®, and Janus-III Facial Analysis System® tools at week 0. In the morning (between 05:00–08:00 Central Indonesia Time), one group cleansed their face using five drops of facial wash, followed by the application of two drops of serum containing GABA 3%, DMAE 2%, Bakuchiol 1%, and Cysteamine 2.5% on both palms. The serum was then applied evenly over the entire face until fully absorbed and left on for one minute. A cream containing the same active ingredients (GABA 3%, DMAE 2%, Bakuchiol 1%, and Cysteamine 2.5%) was applied in an amount equivalent to one fingertip unit (FTU) to the whole face. In the evening (between 19:00–22:00), after cleansing the face again with five drops of facial wash, the same procedure was repeated—application of two drops of the active serum, followed by one FTU of the corresponding cream over the entire face.

In contrast, the other group followed an identical regimen using placebo products. In the morning (05:00–08:00 Central Indonesia Time), participants cleansed their face with five drops of facial wash, then applied two drops of placebo serum on both palms and spread it evenly over the entire face until absorbed, allowing it to rest for one minute. This was followed by the application of one FTU of placebo morning cream over the entire face. In the evening (19:00–22:00), after cleansing with five drops of facial wash, participants applied two drops of placebo serum and then one FTU of placebo night cream, following the same procedure as the morning routine. The subjects were randomly allocated into two groups: the treatment group (Group A) and the control group (Group B). Both participants and investigators were blinded to group allocation.

The Mexameter® MX 18 (Courage Khazaka, Germany) used 16 LEDs to emit light at three wavelengths: 568 nm (green), 660 nm (red), and 880 nm (infrared). The melanin index (MI), which corresponds to the skin melanin level, and the erythema index (EI) were obtained using a computerized examination. The Chromameter® (Konica Minolta, Japan) objectively measured skin color by analyzing the reflection of a xenon lamp perpendicular to the probe at 450 nm, 560 nm, and 600 nm. The resulting parameters were represented by the numbers L, a, and b. The L-value parameter represented the brightness of the skin colour (100 for white and 0 for black). The Janus-III Facial Analysis System® (PIE Inc, South Korea) was a facial analysis system that uses a high-resolution camera to objectively assess various skin issues such as pigmented spots, wrinkles, skin tone, UV spots, and sebum production. All data were analyzed using Statistical Package for Social Sciences (SPSS) version 22.0 (SPSS. Inc) with Unpaired Parametric T-Test was used for normally distributed data, while the Mann–Whitney test was applied for non-normally distributed data. Results were considered statistically significant at $p < 0.05$. All data results were presented in tables and graphs.