A Proof-of-Concept, Placebo-Controlled, Safety, and Efficacy Study of Plant Based Biotin in Healthy Adult Human Subjects with thin, dry, and brittle hair.

NovoBliss Research

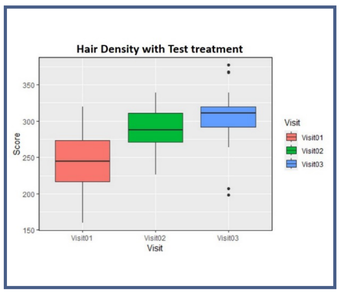
Experimental Design

It was a randomized, placebo-controlled, double-blind, two–arm, single-center, proof-of-concept safety, and efficacy clinical study The objective of this study was to evaluate the effectiveness of the product in Healthy Human Subjects with adequate representation of change in hair density, thickness and scalp condition and reduction of facial wrinkles and fine lines or crow's feet area after usage of product. A total of 54 subjects ages 30 to 55 years were enrolled, and 51 subjects completed the study. This clinical trial has been registered at CTRI [Clinical Trial Registry of India] with the Trial Registered number CTRI/2022/10/046324 [Registered on: 10/10/2022].

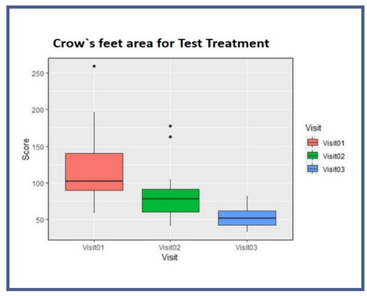
Methodology

The Dermatologist's trained evaluator and physician have determined the subject's eligibility and conducted a clinical evaluation to confirm the subject's general health. Subjects with Fitzpatrick skin type III to VI, Glogau skin age II or III, and mild skin aging as per Physician Global Assessment (PGA) of Skin Appearance using the Griffiths scale was determined by a dermatologist's trained evaluator for the enrolment. The subjects were instructed to take 1 capsule in the morning and 1 capsule at night.

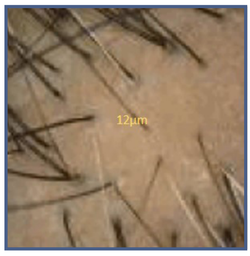
Assessment of efficacy parameters was done before test treatment usage on day 1, and after a product usage on day 28, and day 56 of the study. The SesZen-BioTM was evaluated to check the effectiveness of change in hair density, thickness, and scalp condition, reduction in facial wrinkles, and fine lines of crow's feet area. The effect of the product was assessed in terms of change in Glogau skin age, skin color evenness, improvement in skin elasticity, skin hydration, and skin barrier function, change in serum ferritin, improvement in brittle nails and treatment Perception Assessment after 8 weeks from baseline and also between the treatment and placebo group. Upon completion of the Clinical Phase of the study, all raw data were reviewed, and an excel spreadsheet with raw data was shared with Biostatistician. Statistical analysis was performed by Biostatistician Team. There were no adverse events reported by the subjects/parents, nor by the Investigator throughout the study period.



In the clinical trial, on Day 01 before product, Day 28 (02 Days), and Day 56 (+02 days) of product, the product showed an improvement in total hair density by 18% and 25% at Day 28 and Day 56 respectively with a p-value < 0.01 as compared to placebo.

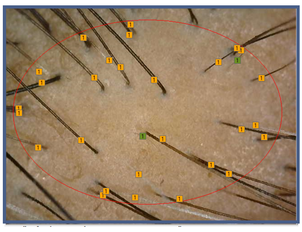


There was a statistically significant reduction observed in the crow feet area wrinkles by 27% on Day 28 and 48% on Day 56 with a p-value <0.01 as compared to the placebo.

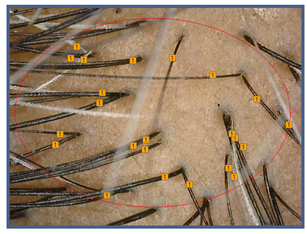


Visit 1 (Day 01)
Hair Thickness - 12 µm

Visit 3 (Day 30)
Hair Thickness - 15 µm



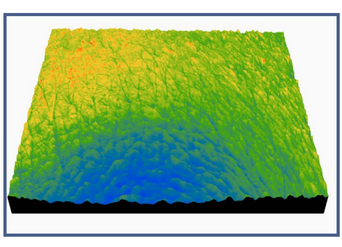
Sub# 24 - Visit 1 (Day 01)
Hair Density – 217sqcm



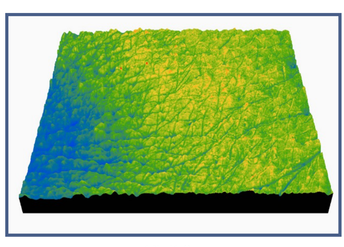
Sub# 24 - Visit 3 (Day 60)
Hair Density – 283sqcm

Visit 1
Crow's feet area wrinkle

Visit 3
Crow's feet area wrinkle



Visit 1
3D image Wrinkles – VisioScan VC20



Visit 3
3D image Wrinkles – VisioScan VC20

Overall Conclusion

As per the Investigator and Dermatologist, the product was found to be efficacious and safe in healthy human adult subjects (30–55 years) with 100% well-being. product which is derived from Sesbania Agati extracts showed an improvement in hair density, hair thickness and scalp keratin in 8 weeks of usage suggesting it stimulates the keratin production which resulted in improved follicle growth. Product also decreased the transepidermal water loss of skin resulting in improvement in skin hydration and skin elasticity. Significant improvement in skin tone and reduction in crow's feet area wrinkles and facial fine lines was observed. There was an overall improvement in appearance of hair and scalp condition.