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RANDOMIZED TRIAL BACKS BIOTIN VITAMIN GUMMIES, DECREASING HAIR-FALL, FASTER HAIR GROWTH, EMPHASIZING NUTRITIONAL SUPPLEMENTATION SIGNIFICANCE

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ABSTRACT

Objective: Hair loss is associated with negative emotional impacts, affecting the well-being of both men and women, leading to stress, diminished body image satisfaction, reduced quality of life, lower self-esteem, and diminished confidence. This research aims to clinically validate the effectiveness of vitamin hair gummies in individuals experiencing hair loss while enhancing overall hair and nail health. **Trial Registration:** The clinical trial was registered with the Clinical Trial Registry-India (CTRI) with the registration number CTRI/2023/03/050199 on March 01, 2023. URL: https://ctri.nic.in/Clinicaltrials/pdf_generate.php. **Methods:** A total of 65 participants with hair loss and diverse hair and nail health issues were included in our study. Subjects were divided into two groups: Group A: Hair Vitamin Gummies, and Group B: Placebo Gummies, in a 2:1 ratio. Treatment duration was of 90 days. **Results:** The findings demonstrate that Hair Vitamin Gummies effectively treat hair loss, positively impacting various parameters related to hair and nail health. The test group exhibited significant increases in hair density (26%), thickness (16%), and length (118.98%), as well as accelerated hair growth rate (108.03%). Additionally, there was a notable reduction in hair fall and dandruff (70.32%). **Limitations:** The study is limited by a small sample size and a relatively short follow-up period. **Conclusion:** This study suggests that Hair Vitamin Gummies are a safe and effective treatment for hair loss and related hair and nail health issues. The unique combination of ingredients in the formulation may synergistically enhance the product's efficacy.

KEYWORDS: Hair growth, Vitamin, Biotin, Hair Fall, Anagen to Telogen Ratio.

INTRODUCTION

A hair loss, formally known as alopecia, can happen for a variety of reasons, including age, hormonal imbalances, high stress, and untreated medical conditions. Nutrition deficiencies can also affect hair growth and structure, necessitating vitamin supplements when dietary approaches fall short. When dietary approaches like dietary modification, fortification, or food provision are unable to achieve adequate intake, vitamin supplements are needed.[1,2] Vitamin gummies are more palatable, convenient to administer, colorful, and come in a variety of flavors to suit the palate. The present research is an attempt of clinical validation of vitamin hair gummies in subjects suffering from hair fall, and to improve hair & nail health.

MATERIAL AND METHODS

Study design

A randomized, double-blind, placebo-controlled clinical study included sixty-five healthy male and female volunteers aged 18 to 35 years. The participants were administered Group A: Hair vitamin gummies (43 subjects) and Group B: Placebo gummies (22 subjects) in 2:1 ratio for 90 days. Investigational Product contained biotin, multivitamins, zinc, selenium, grape seed Extract, sesbania extract. Placebo and interventional gummies were identical in organoleptic characteristics (Figure 1).

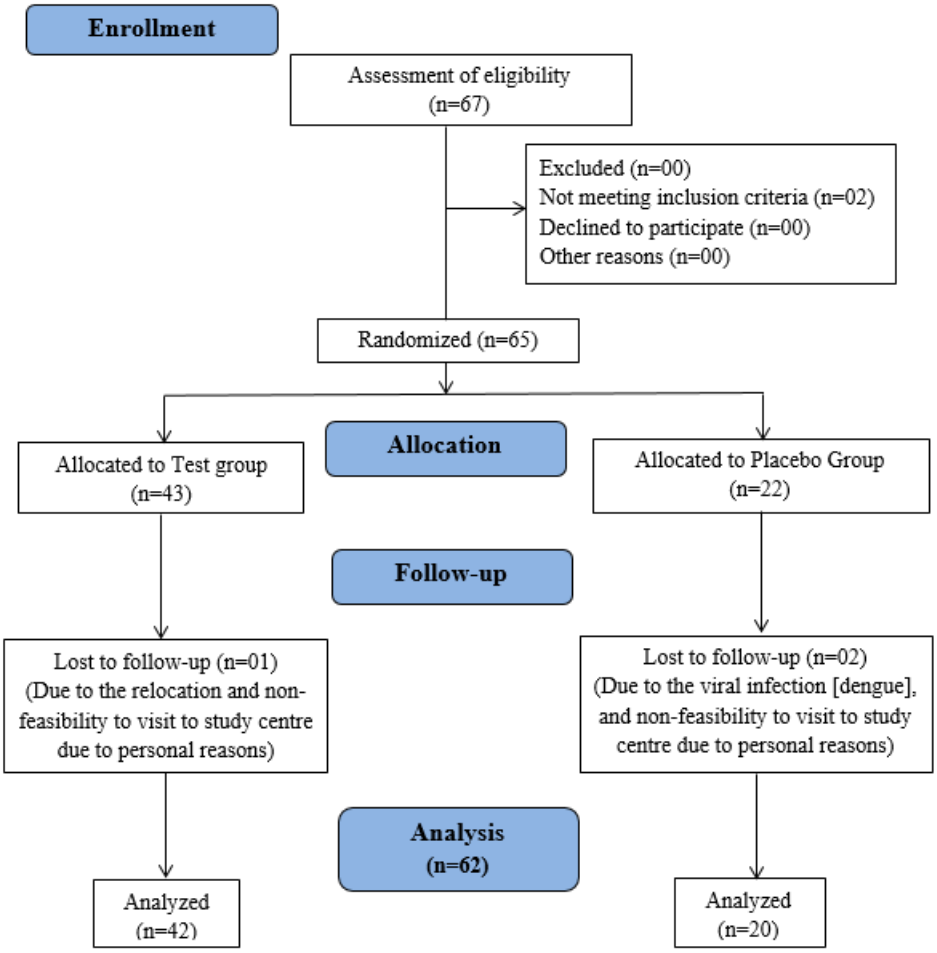

Figure 1: Consort diagram for the study.

METHODOLOGY

Assessment of the safety and efficacy of hair vitamin gummies in reducing hair fall and improving hair and nail health in adults by following parameters:

Parameters such as hair density, terminal and vellus hairs, and anagen to telogen ratios were measured using phototrichogram analyses and assessed at both the screening visit and end of the study. Phototrichogram assessment, was performed in Caselite software using Dino-Lite probe. Subjects were screened utilizing a pictorial grading system and then images capturing hair loss patterns trichoscopically. Evaluation of shredded hairs and hair fall rate by using 60-second comb test and modified hair wash test analyses at both the screening visit and end of the study. Visual analog scale (VAS) score was used to assess scalp related complaints like itching, dandruff or irritation. Assessment of 'self-assessment questionnaire for hair and nail health' was employed at screening and end of the study. This questionnaire comprises 16 questions assessing improvement pattern in skin, hair and nails.

Statistical analysis

Statistical analysis has been done by using SPSS. The primary and secondary endpoints were analyzed using students t-test and one-way ANOVA. The gender distribution data was assessed using the chi-square test.

RESULTS

Demographic characteristics

There were a total of 65 subjects enrolled in the study, comprising 31 males and 34 females. Sixty-two subjects completed the study. Forty-three subjects were enrolled in the test group, while 22 were in the placebo group. The average age in the test group was 24.26 years, and in the placebo group, it was 25.36 years.

Assessment of hair density and follicular density

In this study, target area dimensions were 10.61 sq. mm (0.1 sq. cm.) in all subjects for the assessment by Phototrichogram. Hair density refers to the number of hair strands or follicles present on a specific area of the scalp.

Significant improvement of mean hair density by 26% after 90 days compared to screening. However, in placebo group by 7.88% which was not significant. The difference between both the groups was also found to be statistically significant.

Follicular density refers to the number of hair follicles per unit area of the scalp. Among test group subject's follicular density was increased significantly after 90 days as compared to screening by 21.45%, while there was no significant improvement observed among

placebo group. The difference between both the groups was also significant. (Table 1).

Table 1: Comparison of hair growth related parameters between the groups.

Duration	Test Group	Placebo Group	P value
Hair Density (sq.cm.)			
Screening	324.17±66.41	302.1±73.57	0.242
Day 90	408.24 ± 59.7	325.9 ± 49.9	<0.001*
% Change	26%	7.88%	
P value	<0.001*	0.144	
Follicular Density (sq.cm.)			
Screening	281.6±52.39	284.2± 67.67	0.881
Day 90	342.31 ± 55.9	308.5 ± 49.09	0.024*
% change	21.45%	8.55%	
P value	<0.001*	0.091	
Hair Length (µm)			
Screening	721.88 ± 252.78	559.5 ± 210	0.258
Day 30	1025 ± 331.53	1043.5 ± 319.84	0.928
P value	0.011*	0.066	
Day 60	1322.88 ± 593.87	1296 ± 442.25	0.938
P value	0.019*	0.059	
Day 90	1580.75 ± 772.39	1013 ± 230.13	0.192
P value	0.008*	0.067	
Hair Growth Rate (µm/day)			
Day 30	27.25 ± 15.94	17.5 ± 5.57	0.271
Day 60	35.13 ± 11.21	20.3 ± 7.63	0.491
Day 90	56.69 ± 12.53	17.5 ± 2.65	0.026*
P value	0.003*	0.679	

Data is represented as Mean ± S.D. All parameter analysis was done using Independent Student t test (between group) and Dependent student t test (within group), except hair growth was analysed by using one-way ANOVA (within group).
Significant at p< 0.05.

Assessment of hair growth

Hair growth was assessed in only subjects whom target area of one-square-centimetre was shaved and analyzed. There were total 12 completer subjects among treatment and placebo group.

Hair length refers to the measurement of the distance from the scalp to the tip of an individual hair strand. Hair length was gradually and significantly increased among test group as compared to screening by 41.99%, 83.26% and 118.98% after day 30, day 60 and day 90, respectively. However, in placebo group hair length was increased compared to screening but change was not significant. (Table 1)

As illustrated in Table 1, the hair growth rate exhibited a gradual and statistically significant increase among subjects in the test group. This increase amounted to 28.91% and 108.03% on day 60 and day 90, respectively. Conversely, in the placebo group, the hair growth rate saw an increment of 16% on day 60, with no observable change in growth rate on day 90 compared to day 30. The difference between both the groups was found to be significant after 90 days of the treatment.

Assessment of anagen to telogen ratio

The Anagen to Telogen ratio is a measure used to assess to the balance between the number of hairs in the growth phase (anagen) and the resting phase (telogen) of the hair growth cycle. A higher ratio indicates a higher percentage of hairs in the growth phase, suggesting a healthy hair cycle and good hair density. Conversely, a lower ratio may indicate an increased number of hairs in the resting phase, potentially indicating hair thinning, shedding, or an underlying hair loss condition. 12 subjects were analyzed among treatment and placebo group.

At day 60, in the test group, 05 (62.5%) subjects demonstrated an improved anagen to telogen ratio. While, in the placebo group, no subjects showed improvement.

At day 90, in the test group, 06 (75%) subjects displayed an enhanced anagen to telogen ratio. In the placebo group, 02 (50%) exhibited an improved ratio. The anagen to telogen ratio responses were statistically significant in the test group at both day 60 and day 90.

Assessment of change in terminal & vellus hairs and hair thickness in the target area by Phototrichogram

Terminal hair is defined as thick, coarse, short or long, and pigmented hair that found on the scalp. Vellus hair is defined as fine, short and lightly pigmented hair also found on the scalp.

At screening terminal and vellus hairs were homogenous in both the groups. After 90 days, the mean number of terminal hairs were significantly increased in test group by 55% (from screening 220.52 to 342.10) and in placebo group by 35% (from screening 183.8 to 247.35). If compared, difference between both the groups was significant indicating investigational products effectiveness.

Mean vellus hairs were decreased substantially after 90 days among both test groups by 33% (from screening 103.64 to 69.00) and in placebo group by 31.98% (from screening 118.4 to 80.5). Difference between both the groups was not significant.

After day 90 there was a significant increase of 16% (from screening 52.33 to 60.83) in hair thickness (hair diameter) among the test group subjects, which was only 4.21% (from screening 53.50 to 55.75) placebo-treated subjects. The difference between both the groups was significant.

Assessment of changes in hair fall between groups

In 60 Second Hair Comb Test at screening, mean hair loss was 27.71 among test group which was comparable to 25.50 among placebo group and the difference was not statistically significant.

After 30 days, mean hair loss was significantly reduced by 13.14% among test group and 7.65% in placebo group from screening. If compared, the change was comparable between groups and the difference was not significant. After 60 days & 90 days' treatment, mean hair loss showed a significant decrease of 26.29% & 45% respectively among test group, compared to 12.16% & 14.12% in placebo group. The change was more in test group than placebo group, and difference was statistically significant (Table 2).

The same trend was visible in modified hair wash test. As shown in the Table 2, after 30 days, 60 days & 90 days' treatment, mean hair loss significantly decreased by 8.07%, 17.03%, & 49% respectively among test group, compared to 8.56%, 12.25% &15.42% in the placebo group. The change was more in test group than placebo group, and difference between the groups and within the groups was statistically significant.

Table 2: Comparison of hair fall related parameters between the groups.

60 Second Hair Comb Test (Number of Hairs)			
Duration	**Test Group**	**Placebo Group**	**P value**
Screening	27.71±17.20	25.50±16.71	0.634
Day 30	24.07±15.36	23.55±15.55	0.145
% Change	13.14%	7.65%	
P value	<0.001*	0.086	
Day 60	20.43±14.04	22.40±12.83	0.011*
% Change	26.29	12.16	
P value	<0.001*	0.044*	
Day 90	15.26±10.61	21.90±13.56	0.0002*
% Change	45%	14.12%	
P value	<0.001*	0.019*	
Modified Hair Wash Test (Number of Hairs)			
Duration	**Test Group**	**Placebo Group**	**P value**
Screening	40.40± 25.34	37.95± 21.65	0.710
Day 30	37.14± 24.72	34.70 ± 21.50	0.00005*
% Change	8.07%	8.56%	
P value	<0.001*	0.037*	
Day 60	33.52± 23.16	33.30± 21.47	<0.001*
% Change	17.03%	12.25%	
P value	<0.001*	0.007*	
Day 90	20.62±17.99	32.10 ±17.84	0.00009*
% Change	49%	15.42%	
P value	<0.001*	0.002*	

Data is represented as Mean ± S.D. Analysis was done using an Independent Student t test (between group) and a Dependent Student t test (within group). Significant at p< 0.05.

Assessment of VAS score of scalp-related complaints
Subject reported scalp health during treatment as per 0-10 VAS was analyzed. As per VAS scale '0' indicated no symptom to '10' indicated very severe symptom to the dandruff, itching and irritation.

At screening, the dandruff score was homogeneous in both groups. After 30 days and 90 days of treatment, dandruff was significantly reduced in the test group by 19.63% and 70.32%, respectively, compared to 16.10% and 34.75% in the placebo group. The difference between the groups was also found to be significant.

During the screening, the itching scores exhibited homogeneity in both groups. After 30 days, 60 days & 90 days of treatment, there was a significant reduction in symptom scores in test group by 22.45%, 34.01%, & 64.63% respectively, compared to 25.30%, 28.92%, and 48.19% in placebo group. The reduction was more in test group than placebo group, but difference was not significant.

At screening, the scalp irritation score was homogenous among both groups. Significant reduction was observed in the treatment group as compared to screening which was 75% after 90 days of the treatment. In the placebo group, there was reduction followed by increased in the score was observed but it was not significant at day 60. After 90 days, there was significant reduction of 46.15% as compared to screening. If compared, difference was not significant after 90 days between both the groups.

Assessment of self-assessment questionnaire for hair and nail health
The results provide a detailed insight into the number of subjects and their percentage in whom improvements were observed for various parameters over the course of the study (Table 3).

It is evident that the treatment with hair vitamin gummies outperformed placebo in hair and nail related subject reported parameters.

Table 3: Comparison of Changes in the Hair, Skin and Hair Health Between Both the Groups.

Parameter	Test Subjects showed improvement		Placebo Subjects showed improvement	
	No.	%	No.	%
Overall Hair Volume	31	73.80%	2	10%
Scalp Coverage	31	73.80%	3	15%
Thickness of Hair Body	20	47.67%	1	5%
Softness Of Hair Body	17	40.47%	0	0%
Hair Shine	27	64.28%	3	15%
Number of Hairs Lost on Average Day	24	57.14%	5	25%
Nail strength	22	52.38%	3	15%
Nail Growth Rate	20	47.67%	4	20%
Skin Moisture Retention	11	26.19%	2	10%
Facial Fine Lines and Wrinkles	1	2.38%	1	5%
Skin Softness	16	38.09%	2	10%
Skin Resiliency	11	26.19%	8	40%
Growth of Eyebrow Hair	26	61.90%	5	25%
Growth of Eyelashes	24	57.14%	3	15%
Skin Smoothness	17	40.47%	3	15%
Overall Skin Health	12	28.57%	9	45%

Assessment of tolerability
Adverse events such as mild weakness, hyperacidity, menstrual pain, body pain, wound cut and dengue were observed. Placebo group subject who had mild dengue which led to recovery with rescue medication in tenure of treatment duration. All other adverse events were mild in nature and resolved without any medications during follow-up period. None of the adverse event was related to the investigational products. The investigational products were well tolerated and subjects consumed the treatment within compliance range of 100%

DISCUSSION
In this study, the effectiveness of hair vitamin gummies in reducing hair fall and improving overall hair and nail health was investigated in two groups: test and placebo group. After a 90-day treatment period, significant and clinically meaningful reductions were observed in hair fall measured by 60 second hair comb test and MHWT in both the groups. Moreover, the study found that the treatment with hair vitamin gummies significantly more effective in controlling hair fall compared to placebo gummies. Hair density, follicular density was significantly increased among test group subjects while it was not increased significantly in the placebo group. Hair growth rate was increased gradually yet significantly among test group while in placebo group no significant change was observed throughout the study. Anagen to telogen ratio analysis revealed that there was significantly more number of subjects with improvement

in the test group as compared to placebo group in just 90 days of the treatment. Terminal hairs were significantly increased among test group compared to placebo group. Vellus hairs were significantly and similarly increased among both the groups. Hair thickness was significantly increased among test group while there was no significant increase in hair thickness observed in the placebo group. After 90 days of the treatment, scalp related complaints such as dandruff, itching and irritation were significantly reduced in both groups. Dandruff was significantly reduced in test group as compared to placebo while in both the groups itching and irritation was reduced and the difference was not significant between the groups. The comprehensive self-assessment questionnaire of skin, hair, and nail health collectively emphasized the investigational product's efficacy in inducing positive improvements across these domains in 90 days. Importantly, no clinically or statistically significant changes were observed in vital signs, and no adverse events related to the investigational products were reported throughout the study in either group, highlighting the safety of Hair vitamin gummies. Moreover, good to excellent tolerability of investigational product was reported among all subjects and the around 97-98% compliance was reported in both the groups throughout the study.

In our study, dandruff, itchiness, and irritation reduced significantly in test group after treatment of 90 days indicating Hair vitamin gummies could potentially improve the scalp health.

The investigational product incorporates a range of vital elements such as selenium, zinc, vitamin C, vitamin E, and various B-group vitamins all known for their diverse roles in maintaining optimal hair and scalp health. These components collectively offer multifaceted benefits that could potentially address hair loss concerns comprehensively. Selenium's presence aids in shielding against oxidative stress and free radicals, factors known to impede hair follicle development. Zinc, essential for keratin production, has shown potential in improving hair loss conditions. [3,4] Vitamin C's enzymatic contribution in collagen formation and keratin cross-linking, alongside its antioxidant prowess, combats follicle degeneration. Vitamin E's antioxidant properties aid in restoring damaged follicles and promoting healthy growth. B-group vitamins, particularly B6, are integral for skin development and cysteine incorporation in hair cells. [5,6] Additionally, biotin's incorporation into various hair supplements is widespread, driven by its favorable outcomes observed in other instances of keratin-related phenomena, including onicoschizia and diverse nail disorders. biotin and zinc, have been recognized for countering deficiencies associated with alopecia. These constituents collectively present in the hair vitamin gummies offer a comprehensive approach to reduce hair fall, stimulate growth, and enhance overall hair and nail health presenting a promising approach to hair care. [7,8]

The study's strong point lies in the inclusion of a wide range of essential nutrients known for their roles in hair and scalp health. This holistic approach reflects real-world conditions where multiple factors contribute to these conditions. This comprehensive perspective of addressing both hair and nail health, reflects the potential practical benefits for individuals seeking overall improvement in these aspects. The study demonstrates strength through its implementation of general dietary consultation across both study groups, enhancing the generalizability of the findings. Additionally, the placebo-controlled design not only validates the study results but also contributes to increased robustness, generalizability, and reliability. The study provides positive findings, suggesting that the investigational product has the potential to positively impact hair fall and growth. These preliminary outcomes warrant further investigation with a larger sample size and extended treatment duration to provide more robust insights into its efficacy.

CONCLUSION

The clinical study on the safety of Hair Vitamin Gummies revealed that it was effectively tolerated by subjects when administered orally at a dosage of 1 gummy per day. Overall, the findings from these clinical trials support the potential effectiveness of the ingredients present in Hair vitamin gummies for reducing hair fall and improving various parameters associated with hair growth and nail health. The combination of these ingredients in the formulation may synergistically enhance the product's efficacy, as observed in the present study.

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