A 3-Month, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Ability of Viviscal Dietary Supplement to Promote Hair Growth and Decrease Shedding in Women with Self-Perceived Thinning Hair

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Introduction

Female pattern hair loss is a significant problem affecting a large number of women. Viviscal® Oral Tablets (Lifes2good, Inc., Chicago, IL) is a dietary supplement specifically designed to promote hair growth in women suffering from temporary thinning hair. The objective of this double-blind, placebo-controlled study was to assess the ability of Viviscal to promote the growth of terminal hairs in adult women with self-perceived thinning hair.

Methods

Study Subjects

Women 21-65 years of age with Fitzpatrick photo skin type I-IV and self-perceived thinning hair associated with poor diet, stress, hormone influences or abnormal menstrual cycle were eligible for enrollment.

Study Treatment

Subjects were randomized in double-blind fashion to receive Viviscal Oral Tablets or placebo. Subjects were instructed to take one tablet of their assigned treatment twice daily in the morning and evening following a meal and maintain their normal hair care routine.

Study Procedures

Enrolled subjects were seen at a baseline clinic visit (Visit 1) and a 90-day follow-up visit (Visit 2). At both visits, each subject had their hair washed with a commercial shampoo (Viviscal® Gentle Shampoo) over a sink containing a cheesecloth to catch any shed hairs which were collected and counted. During the Baseline visit, a 4 cm^2 area of the scalp was selected along the frontalis bone where frontal hairline and lateral hairline meet and marked with a black marker. Phototrichograms were obtained of the target area at both visits. Ten terminal hairs in the target area were randomly chosen through-out the area and cut at the surface of the scalp. Digital photographs were obtained to measure hair diameter 1 mm from the cut end of the hair and the hair diameter was measured. Subjects also responded to Quality of Life and Self-Assessment Questionnaires at Visit 2.

Results

Subject Enrollment

Sixty women with a mean (SD) age of 48.6 years (10.0 years; range, 25-65 years) were enrolled and randomized to receive treatment with Viviscal (N=30) or placebo (N=30) and all subjects completed the study.

Primary Endpoint

Among the Viviscal-treated subjects, there was a significant increase in the mean number of terminal hairs from 178.3 (7.8) at baseline to 235.8 (18.4) in the target area at Visit 2 (p<0.0001) but not among placebo-treated subjects (Table 1). There was also a significant increase in the number of vellus hairs in Viviscal-treated subjects (p<0.0001) but not in placebo-treated subjects. The increase in hair regrowth is apparent in the representative subject shown in Figure 1.

Secondary Endpoints

Only the subjects treated with Viviscal had a significant decrease in hair shedding (p=0.002). There was no significant increase in terminal hair diameter among either groups.

Subjects treated with Viviscal obtained significantly higher total scores on the Self-Assessment Questionnaire at Visit 2 (p=0.006) with significant differences between the two groups on 7 of 13 items including Overall Hair Growth, Overall Hair Volume, Scalp Coverage, Thickness of Hair Body, Hair Strength, Growth of Eyebrow Hair and Overall Skin Health (Table 2).

Safety Endpoints

There were no reported adverse events.

Conclusion

Similar to previous studies (1), the ingredients in Viviscal promote hair growth in women suffering from temporary thinning hair. The current study further demonstrated the ability of this product to increase hair diameter and decrease hair loss. Viviscal continues to demonstrate an excellent safety profile.

Reference
1. Ablon G. A double-blind, placebo-controlled study evaluating the efficacy of an oral supplement in women with self-perceived thinning hair. *J Clin Aesthet Dermatol. 2012;5:28.*

Figure 1.

Images from a Viviscal-Treated Subject at Baseline (Left) and Day 90 (Right)

Table 1.

Changes in Hair Growth and Hair Diameter

Viviscal, N=30	Baseline	Day 90	Significance*
Mean Terminal Hair Count (SD)	178.3 (7.8)	235.8 (18.4)	p<0.0001
Mean Vellus Hair Count (SD)	19.6 (2.1)	21.2 (2.2)	p<0.0001
Mean Terminal Hair Diameter, mm (SD)	0.062 (0.009)	0.063 (0.009)	p=NS
Mean Shed Hair Counts (SD)	27.1 (26.6)	16.5 (14.4)	p=0.002

Placebo, N=30	Baseline	Day 90	Significance*
Mean Terminal Hairs (SD)	178.2 (9.6)	180.9 (18.8)	p=NS
Mean Vellus Hairs (SD)	19.8 (1.7)	20.0 (1.9)	p=NS
Mean Terminal Hair Diameter, mm (SD)	0.063 (0.009)	0.062 (0.008)	p=NS
Mean Shed Hair Counts (SD)	23.4 (25.5)	21.9 (20.8)	p=NS

*Repeated measures ANOVA across study days contrasts per treatment group; NS, not significant.
**Baseline versus 90 days .

Table 2.

Self-Assessment Questionnaire Results

Quality	Viviscal, N=30 Day 90	Placebo, N=30 Day 90	Signif.*
1. Overall hair growth	5.03 (0.85)	4.53 (0.68)	p=0.015
2. Overall hair volume	4.97 (0.72)	4.17 (0.79)	p<0.0001
3. Scalp coverage	4.70 (0.14)	4.23 (0.97)	p=0.042
4. Thickness of hair body	4.77 (0.82)	4.20 (0.89)	p=0.013
5. Softness of hair body	4.67 (0.96)	4.33 (0.84)	p=NS
6. Hair shine	4.60 (1.00)	4.37 (0.77)	p=NS
7. Hair strength	4.97 (1.00)	4.33 (0.84)	p=0.013
8. Nail strength	4.97 (1.03)	4.47 (1.11)	p=NS
9. Nail growth rate	4.73 (0.98)	4.40 (0.89)	p=NS
10. Growth of eyebrow hair	4.40 (0.86)	4.00 (0.53)	p=0.033
11. Growth of eyelashes	4.27 (0.69)	4.17 (0.59)	p=NS
12. Skin smoothness	4.50 (0.82)	4.20 (0.81)	p=NS
12. Overall skin health	4.63 (0.85)	4.17 (0.91)	p=0.045

*One-Way Analysis of Variance; NS, not significant.

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