Long-Term Efficacy of a Nutraceutical Supplement for Promoting Hair Growth in Perimenopausal, Menopausal and Postmenopausal Women with Self-Perceived Thinning Hair

Introduction: Hair loss in women increases with age and menopause. The most common diagnosis is female pattern hair loss, also known as androgenetic alopecia, which affects an estimated 40% of women over 60. Hormonal changes of menopause are associated with decreased hair growth rate as well as percentage of hairs and time spent in anagen phase. Here, we present results of a 12-month study assessing the efficacy of a nutraceutical supplement in promoting and improving growth of hairs in perimenopausal, menopausal and postmenopausal women with self-perceived thinning hair.

Study Design

The purpose of the study was to assess the safety and efficacy of an oral supplement with standardized botanicals in improving hair growth in perimenopausal, menopausal and post-menopausal female subjects with self-perceived thinning hair;

- 6-month double-blind, randomized, placebo-controlled
- 6-month open-label extension

At each visit:

- Phototrichograms were obtained of the target area via macrophotography for hair count analysis.
- Hair wash shed count.
- Two-dimensional standardized global photographs of the entire head, hair and target region and used to assist the blinded investigator in grading general hair growth and hair quality (texture, shine, dryness, scalp coverage, hair brittleness and overall appearance) improvement from baseline.



Results

6M and 12M analyses based on 60 subjects;

 33 active 27 placebo

Subjects average age of 55.15 (±6.57) years.

No differences between groups in terms of;

- Demographics,
- General lifestyle; or
- Menopausal symptoms.

Previously reported¹ interim 6-month results showed statistically significant improvements for the active group vs placebo for the number of terminal, vellus and total hairs and shedding at day 90 with further improvement at day 180 (all Ps < 0.005).

Blinded Investigator Global Hair Assessments revealed progressive and significant improvement for the active group vs the placebo group at day 180 on both hair growth and quality scales (P<0.05).



Figure 1: Global photographs of profile views of an active subject at baseline, day 90, day 180 and day 360.

Top: Global photographs of top view **Bottom:** Macrophotographs of selected 1 cm² target area

Methods

Seventy (70) females, age 40-65, who are perimenopausal, menopausal or post-menopausal with self-perceived thinning hair were enrolled in the study.

Primary endpoints included change in the number of:

Evaluated at D90, 180, 270 and 360 via Macrophotography

- Total Hair Count
- Terminal Hair Count
- Vellus Hair Count

Secondary endpoints include;

- Hair Wash Shedding Counts
- Blinded Physician Global Hair Assessments
- Subject Questionnaires

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Results

Among subjects in the active treatment group for 12 consecutive months:

- Mean total hair counts increased significantly and progressively from Day 0 to 360, culminating in a mean increase of **11.7%** (p<0.0001).
- Mean terminal hair counts progressively increased from Day 0 to Day 360, corresponding to a significant **13.4%** improvement (p<0.0001).
- Shedding significantly decreased by 43.2% on Day 180 (p<0.01), remaining stable through Day 360 (p<0.01 vs. baseline)
- Global hair growth improvement ratings increased significantly 43% from Day 90 to 180 (p<0.001) and 25% from Day 90 to 360 (p<0.05).
- Global hair quality improvement ratings significantly increased by 24% from Day 90 to 180 (p<0.05) and by 37% from Day 90 to 360 (p<0.005). A 13% increase was noted from Day 180 to 360 but was not statistically significant

When switched over to the active treatment, subjects initially in the placebo group had:

- 5.1% increase in hair growth (p<0.001)
- 39% decrease in shedding (p<0.0001) from day 180 to 360.
- Global hair growth improvement ratings across 6-month of active treatment for this group increased by 30% (p<0.05) versus 11% when they were taking placebo (p>0.05).
- Global hair quality improvement ratings significantly increased by 40% (p<0.001) versus 11% when they were taking placebo (p>0.05).

Safety Assessment: Daily administration of the nutraceutical supplement was well-tolerated. There were no unanticipated AEs.



Conclusion

With progressive aging of society and the fact that women now spend approximately one-third of their lives in the postmenopausal period, research into interventions for menopausal symptoms including hair thinning are needed, especially since therapeutic options are so limited. The results of this study showed significant and progressive improvements in hair growth during 6 and 12 months, demonstrating the ability of a nutraceutical supplement to effectively improve hair growth and quality in peri-, menopausal and postmenopausal women with thinning hair.

Reference: 1 Ablon G, Kogan, S. A Randomized, Double-Blind, Placebo-Controlled Study of a Nutraceutical Supplement for Promoting Hair Growth in Perimenopausal, Menopausal, and Postmenopausal Women With Thinning Hair. J Drugs Dermatol. 2021;20:55-61.

Conflicts of interest/Disclosure:

Dr. Glynis Ablon received a research grant for the study from Nutraceutical Wellness LLC. All other authors are employees by Nutraceutical Wellness LLC