A Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy and Safety of an Oral Supplement with Standardized Botanicals to Promote Hair Growth in Women going through Menopausal Transition - Results from Six Month Interim Analyses.

Introduction: In the United States, 40% of all people with hair loss are women. The prevalence of generalized hair loss/thinning increases with advancing age and is most common among post-menopausal women. Female hair loss is a complex process with a poorly understood etiology that has been described by some as an accelerated aging process during which the environment of hair follicles is modified by hereditary, inflammatory, hormonal, or vascular factors. Current therapies often target sole causes although the actual cause appears to be multifactorial and increases after menopause. Nutrafol Women's Balance[®] oral supplement with patented Synergen Complex Plus[®] was developed to improve hair growth and hair quality specifically for women going through menopausal transition and beyond.

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



Results



Figure 1: Active subject at baseline, day 90, and day 180 **Top:** Global photographs of profile view. **Bottom:** Macrophotographs of selected 1 cm² target area.



Figure 2: Active subject at baseline, day 90, and day 180 **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 and D180 months via Macrophotography (Canon Power Shot G16 with 3GEN Dermlite FOTO Pro)

- 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

6M Interim analysis is 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.

Active subjects reported;

- 97% felt it was convenient to add 4 capsules to their daily routine
- 94% felt it was more convenient to take a capsule than apply topical

Safety Assessment: There were no unanticipated AEs.



Figure 3: Change in **total** hair count was statistically significant from day 0 to day 90 and day 180, and from day 90 to day 180 for active versus placebo at (p<0.01).

Primary Endpoint





Figure 4: Change in **vellus** hair count was statistically significant from day 0 to day 180 and from day 90 to day 180 for active versus placebo (p<0.05).

References

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Conclusion

The results of this study showed that the administration of a novel supplement with bio-optimized phytoactive ingredients to specifically address the multiple underlying factors that compromise hair growth was safe and effective in improving hair growth and quality in women going through menopausal transition.



. Peacock K, Ketvertis KM. Menopause. In: StatPearls. Treasure Island, FL: StatPearls Publishing; April 27, 2020.

Conflicts of interest/Disclosure: