NUTRAFOL

A 6-Month, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Safety & Efficacy of Nutrafol Nutraceutical to Promote Hair Growth in Women with Self-Perceived Thinning Hair

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Introduction

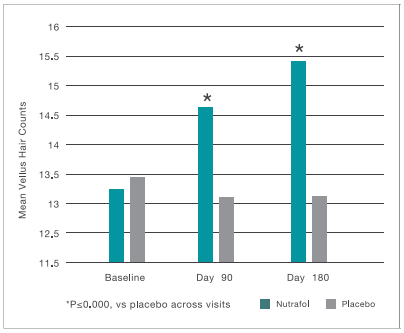
Hair loss is a chronic and progressive condition affecting at least 50% of women by age 50 and 40% of men by age 35.1 Nutrafol is a novel nutraceutical with multi-targeting Synergen Complex, composed of patented standardized botanicals with clinically proven anti-inflammatory, DHT-inhibiting, stress adaptogenic and antioxidant properties. The objective of this study was to evaluate the safety and efficacy of daily supplementation with Nutrafol to promote hair growth in women with self-perceived thinning hair.

Methods

Forty healthy women 21-65 years old with Fitzpatrick skin types I-IV and self-perceived thinning hair were enrolled and randomized in double-blind fashion to receive Nutrafol (n=26) or placebo (n=14) once daily. The subjects were evaluated at baseline, Day 90 and Day 180. A 2 cm2 area of the scalp was selected and marked via triangulation along the juncture of the frontal and lateral hairline. The primary endpoints evaluated were a change in the number of vellus and terminal hairs on phototrichogram analysis at Day 90 and Day 180. Secondary endpoints included physician global hair assessments on hair growth and quality and subjects also completed Self-Assessment, Ease of Use and Quality of Life questionnaires at each visit.

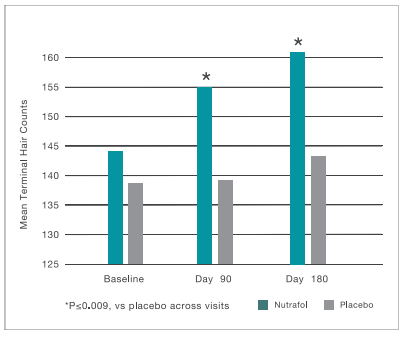
Results

Figure 1.
Improvement in Vellus Hair Count



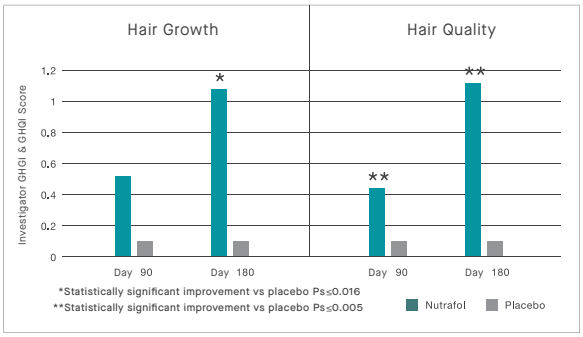
There was a significant increase in the number of vellus hairs in the target area at both Day 90 and Day 180 over baseline in the Nutrafol group vs. placebo (p<0.0001). At Day 180, this translated into a 16.2% improvement in vellus hair growth for the Nutrafol group vs. a decrease of 2.3% for placebo.

Figure 2.
Improvement in Terminal Hair Count.



There was a significant increase in the number of terminal hairs in the target area at both Day 90 and Day 180 over baseline in the Nutrafol group vs placebo (p<0.0001). At Day 180, this translated into a 10.3% improvement in terminal hair growth for the Nutrafol group vs only 3.5% for placebo.

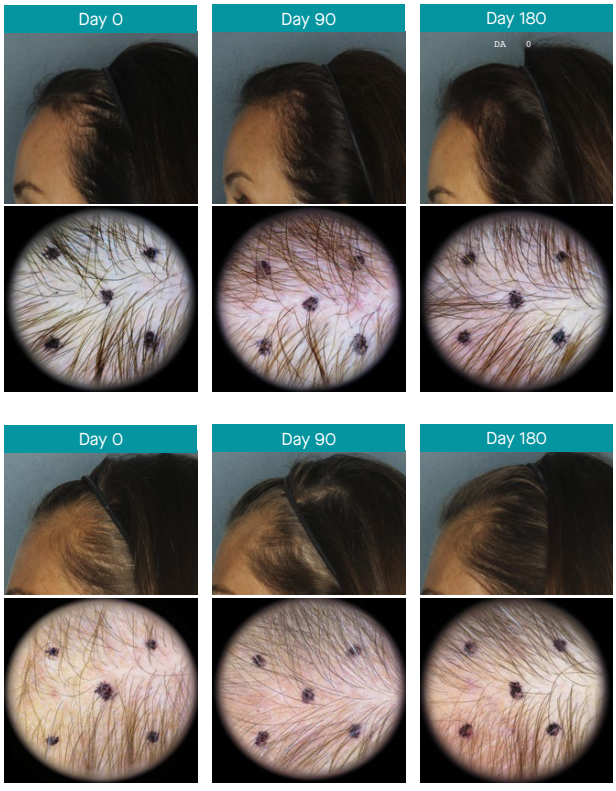
Figure 3.
Global Improvement in Hair Growth & Quality by Investigator Grading.



Global Improvement in Hair Growth Results

The Nutrafol group had statistically significant improvement versus placebo in hair growth at Day 180 as graded by an investigator. The mean hair growth global improvement scale scores were 1.08 (1.1) for the Nutrafol group and 0.08 (0.76) for the placebo group (p<0.016).

Figure 4.
Images from Nutrafol-treated Subjects at Baseline and Day 180.



Global Improvement in Hair Quality Results

There was significant improvement in the Nutrafol group compared to the placebo group at both Day 90 and Day 180. At Day 180 the mean hair quality global improvement scale scores were 1.12 (0.87) for the Nutrafol group and 0.08 (0.76) for the placebo group (p<0,05). Hair quality was rated based on hair brittleness, dryness, texture, shine, scalp coverage and overall appearance.

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Figure 5.
Self-Assessment Questionnaire Results After Taking Nutrafol for Day 180

% of Subjects Improved	Quality
80.8%*	Overall hair growth
73.1%*	Overall hair volume
80.8%*	Thickness of hair body
23.1%*	Hair color
76.9%*	Amount of noticeable new hair
73.1%*	Hair growth rate
15.4%*	Stress level
15.4%*	Anxiety level
19.2%*	Overall well-being
23.1%*	Skin Smoothness
26.9%*	Overall skin health

Safety Assessment

There were no reported adverse events or side effects. Subjects found it to be well tolerated and easily incorporated into their daily routines.

Conclusion

The results of this study indicate that daily supplementation with Nutrafol nutraceutical resulted in increased hair growth in women with self-perceived thinning hair. A vast majority of treated subjects also reported positive results in key hair quality and wellness attributes. These results further underscore the unique synergistic ability of Nutrafol ingredients to address hair loss by targeting its underlying causes (inflammation, stress, DHT and oxidative damage). Nutrafol provides a novel, safe and effective therapeutic option for improving hair growth in women with thinning hair.