

## Official Propecia 5 Year Trial Results

Posted by : admin on Oct 10, 2007 - 04:52 PM

Hair Loss News

Complete analysis of Propecia 5 year results on side effects, hair count, maintenance, and regrowthThe longest running hair loss treatment clinical trial in history shows continued effectiveness in Propecia after 5 full years of use...New Five-Year Study with Propecia Showed That the 'Hair Count' Gap Grew Over Time Between Men Who Treated Hair Loss with Propecia, Compared to Men Who Didn't

The longest controlled clinical trial of a hair loss treatment ever reported showed that men who took Propecia (finasteride 1 mg) compared to men who took a placebo had a considerable difference in their hair counts after five years, according to data presented at the 59th Annual Meeting of the American Academy of Dermatology.

The new study showed a difference of 277 hairs in a one-inch diameter circle of scalp in favor of men treated with Propecia for five years (n=219) vs. those who received a placebo (n=15). Baseline hair counts of all men at the start of the study averaged 876 hairs in the one-inch diameter circle.

"This study provides new, long-term scientific data that Propecia helped the majority of men with predominantly vertex male pattern hair loss keep the amount of hair they have," said Keith Kaufman, M.D., senior director, Clinical Research, Merck Research Laboratories. "The study also was the first controlled clinical trial to evaluate the course of untreated hair loss over a five-year period and to show the progressive nature of male pattern hair loss."

Made by Merck & Co., Inc., Propecia is indicated for the treatment of certain types of hair loss in men only, based upon two-year studies. Propecia is a once-a-day treatment and is the only pill for male pattern hair loss approved by the Food and Drug Administration. Hair loss affects approximately 30 million men in the United States. Propecia is not indicated for use in women or children.

The five-year data are from investigational extension studies of double-blind placebo-controlled clinical trials that first demonstrated the safety and efficacy of Propecia in 1,553 men age 18 to 41 with mild-to-moderate male pattern hair loss (androgenetic alopecia) in the vertex region (top of the head). Efficacy in bi-temporal recession (hair loss at the temples) has not been established. Men who entered the initial 12-month studies of Propecia were randomized to receive either Propecia (n=779) or placebo (n=774). The initial 12-month studies were extended on an annual basis, with only a small number of men remaining on placebo in subsequent years, as specified in the study design. Men who completed each one-year extension were given the opportunity to enroll in the next one-year extension, for up to five years. The five-year data presented focused on the results of men who continued on the same therapy -- either Propecia or placebo -- for the entire five years.

### Five-year efficacy results

Continued on the next page....

The studies assessed the efficacy of Propecia by four separate endpoints: hair counts in a one-inch diameter circle of the scalp; assessments of "before" and "after" photographs by a panel of dermatologists; patient questionnaires and investigator assessments of changes in scalp hair

growth. The effectiveness of Propecia vs. placebo was demonstrated as follows:

**Hair count:** At the start of the studies, baseline hair counts averaged 876 hairs in a one-inch diameter area of scalp. By the end of the first year, men taking Propecia had an average of 126 more hairs than men taking placebo. This difference continued to grow, and, by the end of the fifth year, the net difference between the groups increased to 277 hairs in favor of the men taking Propecia. At the end of the fifth year, 65 percent of men taking Propecia (n=219) maintained or improved their hair count compared to their hair count at the start of the studies, while all of the men on placebo (n=15) lost hair count.

**Before and after photos:** The panel of dermatologists who reviewed standardized clinical photographs of men treated with Propecia (n=279) and men on placebo (n=16) at the end of the five-year study rated 90 percent of men treated with Propecia as having had no further visible hair loss compared to baseline vs. 25 percent of men on placebo.

**Patient questionnaires:** Questionnaires completed at five years by men on Propecia (n=284) and by men on placebo (n=15) showed that men treated with Propecia indicated a higher level of satisfaction with the appearance of: their hair overall (63 percent vs. 20 percent), the hair on top of their heads (59 percent vs. 13 percent) and their frontal hairline (48 percent vs. 7 percent). Men treated with Propecia were more likely to say that: their bald spot was getting smaller (61 percent vs. 20 percent); the appearance of their hair had improved (77 percent vs. 40 percent); they had experienced increased hair growth (75 percent vs. 40 percent) and their hair loss had slowed (90 percent vs. 67 percent).

**Investigator assessments:** Physician investigators who evaluated the men treated with Propecia (n=279) and men on placebo (n=13) at the end of five years determined that 77 percent of the men treated with Propecia had increases in scalp hair, compared with 15 percent of men on placebo.

### **Five-year safety profile**

The five-year study confirmed the excellent safety profile of Propecia. In the initial 12-month clinical studies, the following side effects were the most common and reported by a very small number of men: less desire for sex (1.8 percent vs. 1.3 percent on placebo), difficulty in achieving an erection (1.3 percent vs. 0.7 percent on placebo) and a decrease in the amount of semen (0.8 percent vs. 0.4 percent on placebo). These sexual side effects went away in all men who discontinued therapy because of them and also disappeared in most (56 percent men who chose to continue taking Propecia through the fifth year of the study. By the end of the fifth year, the incidence of those side effects was less than or equal to 0.3 percent in men who continued treatment with Propecia vs. men on placebo.

- For more information on Propecia, view our Propecia Product Review
- Discuss Propecia with others: Antiandrogen Forums
- Looking to buy Propecia online? Propecia Shop

HLT