
Efficacy, safety, and tolerability of dutasteride 0.5 mg once daily in male patients with male pattern hair loss: A randomized, double-blind, placebo-controlled, phase III study

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Background: Dutasteride (Avodart) is a dual inhibitor of both type I and type II 5 alpha reductases, and thus inhibits conversion of testosterone to dihydrotestosterone, a key mediator of male pattern hair loss.

Objectives: The aim of this randomized double-blind phase III study was to compare the efficacy, safety, and tolerability of dutasteride (0.5 mg) and placebo for 6 months of treatment in male patients with male pattern hair loss.

Methods: A total of 153 men, 18 to 49 years old, were randomized to receive 0.5 mg of dutasteride or placebo daily for 6 months. Efficacy was evaluated by the change of hair counts, subject assessment, and photographic assessment by investigators and panels.

Results: Mean change of hair counts from baseline to 6 months after treatment start was an increase of 12.2/cm² in dutasteride group and 4.7/cm² in placebo group and this difference was statistically significant ($P = .0319$). Dutasteride showed significantly higher efficacy than placebo group by subject self-assessment and by investigator and panel photographic assessment. There was no major difference in adverse events between two groups.

Limitations: The study was limited to 6 months.

Conclusions: This study clearly showed that 0.5 mg of dutasteride improved hair growth and was relatively well tolerated for the treatment of male pattern hair loss. (J Am Acad Dermatol 2010;63:252-8.)

Key words: androgenetic alopecia; dutasteride; male pattern hair loss; treatment.

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Male pattern hair loss (MPHL) is a common, androgen-induced, progressive disorder in genetically predisposed subjects. Frequency and severity of MPHL increase with age and approximately 80% of Caucasian men have some sign of MPHL by the age of 70 years.^{1,2} Many men regard hair loss to be an unwanted, distressing experience that diminishes their body image and adversely affects quality of life.³

Human skin, sebaceous glands, and hair follicles contain the 5 alpha reductase (5AR): 5AR enzyme system, which is needed to convert testosterone to dihydrotestosterone (DHT), the primary androgen responsible for MPHL.^{4,5} There are two 5AR isoenzymes: type I 5AR is widely expressed especially in skin, including scalp, whereas type II 5AR is present

in hair follicles and prostate.⁶⁻⁸ Dutasteride (Avodart) is a dual inhibitor of both type I and type II 5AR; it has been found to improve symptomatic benign prostatic hyperplasia and is well tolerated at doses of 0.5 mg daily for 4 years.⁹⁻¹¹ Phase II study of dutasteride in MPHL has been conducted, and a clear dose response was found between dutasteride and increased hair growth.¹² This dose response was found to be correlated with a reduction of observed levels of DHT in scalp. At a dose of 0.5 mg or more, dutasteride showed a greater increase in target area hair count compared with control after 12 and 24 weeks of treatment.¹² However, the patients treated with a daily dose of 2.5 mg of dutasteride showed increase of adverse events of decreased libido compared with the 0.5 mg of dutasteride group.

Currently, only finasteride (1 mg) and minoxidil solution are approved by the Food and Drug Administration for the treatment of MPHL,¹³⁻¹⁵ while few studies have been conducted on dutasteride for the treatment of MPHL.^{12,16,17} Furthermore, no phase III, randomized controlled study has been conducted on the treatment of MPHL with dutasteride. Here we conducted a randomized, double-blind, placebo-controlled phase III study, aiming to compare the efficacy, safety, and tolerability of a single daily dose of 0.5 mg of dutasteride for 6 months versus placebo in male patients with MPHL.

METHODS

Patient population

Men of 18 to 49 years of age, with mild to moderate androgenetic alopecia (IIIv, IV, V modified Norwood-Hamilton classification) were enrolled in this study. The exclusion criteria applied were: a significant abnormality during a physical or laboratory evaluation, a history of topical minoxidil or any androgenic or antiandrogenic treatment during the previous 6 months or finasteride treatment within 12 months, or previous use of dutasteride. All patients were instructed not to change their hairstyle or hair color during the study. The institutional review boards approved the study protocol and written informed consent was obtained from the subjects before participating in this study.

Study design

This was a multicenter, double-blind, placebo-controlled study. It consisted of a screening phase (21 ± 7 days before randomization), a treatment phase (6 months), and a 4-month follow-up phase. After initial screening visit, 153 eligible men were randomly assigned to dutasteride (0.5 mg) daily or placebo daily for 6 months. Subjects visited the hospital at 3, 6, and 10 months after treatment start.

Efficacy assessment

The primary end point was hair growth based on hair counts, as assessed using macrophotographic phototrichogram technique on the vertex at 6 months.¹⁸ The secondary end points were hair growth based on hair counts at 3 months, subject self-assessment of hair growth at 3 and 6 months, and photographic assessment by investigators and

panels of changes in hair growth at 3 and 6 months.

Hair count

Total hair counts including terminal and vellus hair were measured on 1-cm² circular areas of clipped hairs, selected from the anterior edge of the balding area on the vertex. Before macrophotography of this area, hairs were clipped over 1.9-cm diameter circle using a plastic transparent template. A small cosmetic ink tattoo in the center of the circle was used as a marker to identify the area of hair counting. Macrophotographs of the target area were taken with a camera system developed by Canfield Scientific Inc (Fairfield, NJ).³ A technician converted the photographs into dot maps, and these were converted to hair counts using a computer imaging system. Hair counts were measured at baseline and after 3 and 6 months of treatment.

Subject self-assessment

After 3 and 6 months of treatment, each subject was requested to perform self-assessment of his hair growth and the appearance of his scalp. Photographs on the vertex scalp were taken at screening, and 3 and 6 months. At 3 and 6 months, subjects were asked to complete the hair growth index (HGI). HGI consists of two parts as follows.

Without photographs, the subjects completed part A of the HGI at each visit, which consisted of 4

CAPSULE SUMMARY

- A total of 153 men with male pattern hair loss were randomized to receive 0.5 mg dutasteride or placebo daily for 6 months.
- Mean change of hair counts from baseline to 6 months after treatment start in dutasteride group (12.2/cm²) was significantly more increased than in the placebo group (4.7/cm²).
- There was no major difference in drug-related adverse events between the dutasteride group [5 of 73 (6.9%)] and the placebo group [7 of 75 (9.3%)].

Abbreviations used:

5AR:	5 alpha reductase
DHT:	dihydrotestosterone
HGI:	hair growth index
MPHL:	male pattern hair loss

questions surveying the amount of hair loss, maintenance of hair loss, overall appearance of the hair, and maintenance of hair. Part B of the HGI was completed in conjunction with the photographs at each visit, and included 4 other questions regarding the amount of hair thinning area, amount of hair covering the scalp, amount of hair, and appearance of the thinning area.

Investigator and panel photographic assessments

Standardized photographs of the vertex scalp were taken fixing the head in a stereotactic positioning device at screening and after 3 and 6 months of treatment. A panel of 3 dermatologists and the investigators independently assessed the change in hair growth using a 7-point scale (-3 = greatly decreased, -2 = moderately decreased, -1 = slightly decreased, 0 = no change, $+1$ = slightly increased, $+2$ = moderately increased, $+3$ = greatly increased).

These assessments were performed by comparing vertex 35-mm global photographs obtained during initial screening with those obtained at 3 and 6 months of treatment.

Safety assessments

Safety assessment was performed using the results of physical examinations, laboratory evaluations, and reports of sexual function and adverse events. Sexual function was assessed by asking subjects to complete the problem assessment domain of the sexual function inventory at baseline and at 3, 6, and 10 months of treatment. The problem assessment domain is one of 5 scales used in the sexual function inventory. It consists of 3 items that evaluate the extent to which the subject perceives the following to have been problematic: (1) lack of sex drive; (2) ability to obtain and maintain erections; and (3) ejaculation. Three items were summed to yield a score.

Statistical analysis

Analysis was carried out using software (SAS, Version 9, SAS Institute Inc, Cary, NC) on an intention-to-treat basis. All patients who received one dose of the study drug and underwent at least one post-baseline assessment of any efficacy variable were included. *P* values of less than .05 were considered statistically significant. Descriptive data are presented

as means or as mean changes from baseline \pm 1 SD. Data were compared using Wilcoxon rank sum test, using χ^2 test, and by analysis of covariance.

RESULTS

Patient numbers at various stages of the study are summarized in Fig 1. A total of 153 subjects from 4 centers were enrolled in the study. A total of 148 subjects (dutasteride: 73, placebo: 75) were selected out of those people and included in the intention-to-treat group; the 5 subjects who dropped out before first efficacy assessments were excluded.

Among the intention-to-treat group, a total of 131 subjects (dutasteride: 64, placebo: 67) completed the study, and 17 subjects did not complete the study. The reasons for dropping out included the following: adverse event ($n = 2$), did not meet eligible criteria ($n = 2$), lost to follow-up ($n = 1$), and major protocol deviation ($n = 12$).

Demography

Subject demographics are summarized in Table I. Difference in baseline characteristics of dutasteride and placebo groups was not statistically significant. The mean age was 37.8 years in dutasteride group and 38.4 years in placebo group. The most common type of MPHL in both groups was type IIIv, followed by type V and type IV.

Hair count

The mean change in hair count after 6 months of treatment was significantly greater in the dutasteride group ($12.2/\text{cm}^2$) compared with the placebo group ($4.7/\text{cm}^2$) (Fig 2 and Table II). This difference was statistically significant ($P = .0319$). The mean change in hair count from baseline to 3 months after initial treatment was not statistically significantly different between the two groups ($P = .4647$). The hair counts continuously increased during 6 months of treatment in the dutasteride group. However, in the placebo group, hair counts increased at 3 months and then decreased at 6 months compared with those at 3 months.

Subject self-assessment

Global self-assessments of hair regrowth (part A, without photographs) showed that overall appearance (thickness, hair quality, and amount) and the maintenance of hair were significantly different between dutasteride and placebo groups. Global self-assessment of the regrowth of hair by using photographs also showed significant difference between the two groups. Improvement ratio of appearance of hair by subject assessment at 6 months, defined by combining all the ratios from "slightly better" to "much better" was 71.2% (52/73) in dutasteride group and 36.0% (27/75) in placebo group (Fig 3).

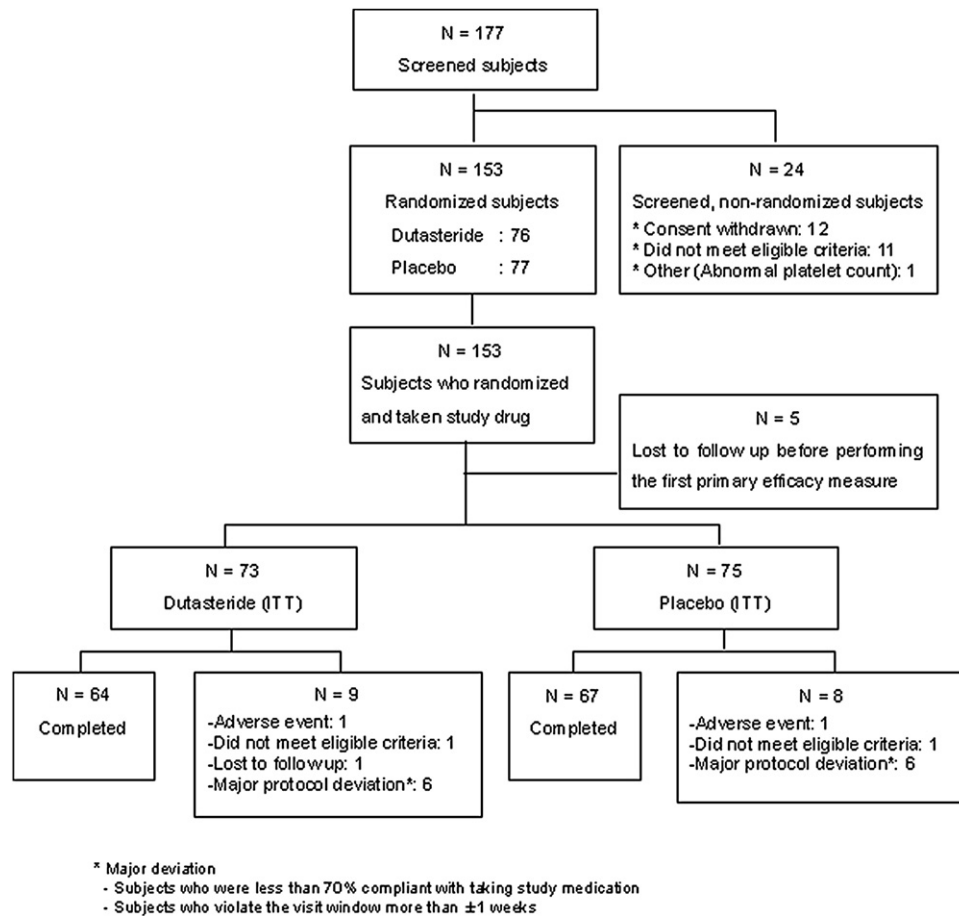


Fig 1. Disposition of subjects

Table I. Demographic characteristics at screening

Characteristics	Dutasteride (N = 73)	Placebo (N = 75)	P value
Age, y			
Mean	37.8 ± 7.1	38.4 ± 6.6	.5842*
Weight, kg			
Mean	73.7 ± 8.2	73.1 ± 11.8	.2738*
Height, cm			
Mean	172.5 ± 5.2	172.7 ± 5.4	.6371 [†]
Type of MPHL			.9848 [‡]
IIIv	38 (52.0%)	38 (50.7%)	
IV	14 (19.2%)	15 (20.0%)	
V	21 (28.8%)	22 (29.3%)	

MPHL, Male pattern hair loss.

*Wilcoxon rank sum test.

[†]Unpaired t test.

[‡]Chi-square test.

Investigator and panel photographic assessments

Investigator photographic assessments on vertex scalp showed greater improvement in the dutasteride group than in the placebo group at 3 and 6

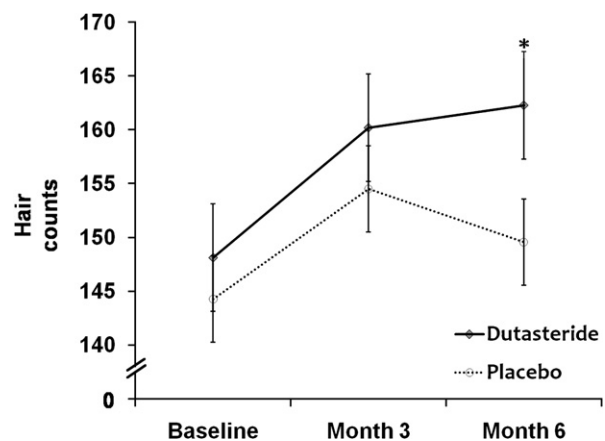


Fig 2. Mean hair count (1 cm²) from baseline to 3 and 6 months of treatment with placebo and dutasteride (0.5 mg) in intention-to-treat population. Mean change in hair count after 6 months of treatment was statistically significantly greater in dutasteride group compared with placebo group. **P* < .05, mean ± SEM.

months after treatment (*P* = .0001, *P* < .0001) (Table III). The improvement ratio of investigator photographic assessment at 6 months was 61.6% (45/73) in

Table II. Hair count (1 cm²) change from baseline to month 6 (intention to treat = 148)

Hair count	Dutasteride	Placebo	P value
	Mean ± SD (n)	Mean ± SD (n)	
Baseline	148.1 ± 36.3 (73)	144.3 ± 32.3 (75)	
Mo 6	162.3 ± 38.5 (70)	149.6 ± 34.4 (73)	
Mo 6-baseline	12.2 ± 23.6 (70)	4.7 ± 16.8 (73)	.0319* [†]
Dutasteride-placebo (95% CI)	7.5 ± 20.4 (0.75-14.3)		

CI, Confidence interval.

*Unpaired t test.

[†]Statistically significant difference.



Fig 3. **A**, Baseline photograph in patient with male pattern hair loss (Norwood-Hamilton type V) of dutasteride group. **B**, Clinical improvement after 6 months of treatment in same patient.

the dutasteride group and 20.0% (15/75) in the placebo group. Mean scores awarded by investigators using the 7-point scale at 3 and 6 months after treatment were 0.71 and 0.78 in the dutasteride group and 0.23 and -0.21 in the placebo group, respectively, and these group differences were statistically significant ($P = .0008$, $P < .0001$) (Table IV). Similarly, the result of the panel's photographic assessment indicated that the dutasteride group showed significant improvement compared with the placebo group (data not shown).

Safety assessments

In all, 36 of 73 subjects (49.3%) in the dutasteride group and 32 of 75 (42.7%) in the placebo group experienced an adverse event (Table V). Among these adverse events, one serious adverse event (thyroid cancer) occurred in the placebo group.

Drug-related adverse events were reported in 5 of 73 subjects (6.9%) in the dutasteride group and 7 of 75 (9.3%) in the placebo group. The total number of adverse events and drug-related adverse events during the study were not significantly different between the two groups ($P = .4171$, $P = .5799$). The most commonly reported adverse event was nasopharyngitis (dutasteride: 12/73, placebo: 7/75). The most common drug-related adverse event was sexual dysfunction, which occurred for 3 of 73 (4.1%) in dutasteride group and 2 of 75 (2.7%) in placebo group. Both erectile dysfunction and ejaculation disorder was noted in one subject in placebo group. Laboratory evaluations, vital signs, and physical examination findings were similar between the two groups. Sexual function assessment findings in the two groups were not significantly different at baseline, or at 3, 6, and 10 months after treatment.

Table III. Distribution of investigator assessment (intention to treat = 148)

Investigator assessment	Mo 3		Mo 6	
	Dutasteride n (%)	Placebo n (%)	Dutasteride n (%)	Placebo n (%)
Greatly decreased	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Moderately decreased	1 (1.4)	1 (1.3)	0 (0.0)	8 (10.7)
Slightly decreased	0 (0.0)	13 (17.3)	4 (5.5)	16 (21.3)
No change	28 (38.4)	30 (40.0)	24 (32.9)	36 (48.0)
Slightly increased	35 (48.0)	30 (40.0)	31 (42.5)	14 (18.7)
Moderately increased	8 (11.0)	1 (1.3)	12 (16.4)	1 (1.3)
Greatly increased	1 (1.4)	0 (0.0)	2 (2.7)	0 (0.0)
<i>P</i> value	.0001*†		<.0001*†	

*Fisher exact test.

†Statistically significant difference.

Table IV. Average investigator assessment (intention to treat = 148)

Investigators assessment (score)	Dutasteride	Placebo	<i>P</i> value
Mo 3			
Mean ± SD	0.71 ± 0.77	0.23 ± 0.80	.0008*†
Mo 6			
Mean ± SD	0.78 ± 0.89	-0.21 ± 0.92	<.0001*†

*Wilcoxon rank sum test.

†Statistically significant difference.

DISCUSSION

In this phase III study, 0.5 mg of dutasteride was found to be significantly more effective than a placebo in men aged 18 to 49 years with MPHL as assessed by hair counts, subject self-assessment of changes in hair growth, and investigators and panels using photographs. The primary study end point was to measure the mean change in hair count/cm² circular area from baseline to 6 months. The dutasteride group showed a mean increase of 12.2/cm² (8.2%), the placebo group showed a mean increase of 4.7/cm² (3.2%), and this difference was statistically significant (*P* = .0319).

In this study, hair counts increased in both dutasteride and placebo groups after 3 and 6 months of treatment compared with baseline. However, a statistically significant difference was observed between the two groups only at 6 months. Although the reason for an increase of hair count in the placebo group, especially at 3 months, is unclear, we think

Table V. Summary of adverse event with onset after randomization

AE	Dutasteride (N = 73)	Placebo (N = 75)	<i>P</i> value
	n (%) [case]	n (%) [case]	
Treatment emergent AE	36 (49.3) [75]	32 (42.7) [60]	.4171*
Serious AE	0 (0.0) [0]	1 (1.3) [1]	
Drug-related AE	5 (6.9) [8]	7 (9.3) [11]	.5799*
Severity	n (%)	n (%)	
Mild	66 (88.0)	57 (95.0)	
Moderate	9 (12.0)	3 (5.0)	
Severe	0 (0.0)	0 (0.0)	
Discontinued because of AE	1 (1.4)	1 (1.3)	
Sexually related AE	3 (4.1) [3]	3 (4.0) [4]	
Sexual dysfunction	3 (4.1) [3]	2 (2.7) [2]	
Erectile dysfunction	0	1 (1.3) [1]	
Ejaculation disorder	0	1 (1.3) [1]	

AE, Adverse event.

*Chi-square test.

that it might be related to a seasonal factor.^{19,20} In the scalp, the proportion of hair follicles in the anagen stage reaches a peak of more than 90% in March and then decreases steadily to reach a trough in September. During this cycle, the number of shed hairs peaks in August and September.¹⁹ In this clinical trial, many subjects were enrolled during early spring.

Dutasteride inhibits both type I and II 5AR, whereas finasteride inhibits only type II 5AR. Furthermore, dutasteride is 3 times more potent than finasteride at inhibiting type II 5AR and 100 times more potent at inhibiting type I 5AR.²¹ In addition, dutasteride can reduce serum DHT by more than 90%,^{11,21} whereas finasteride decreases serum DHT by 70%.²² Therefore, theoretically dutasteride would be expected to be more effective than finasteride for treating patients with MPHL. However, few reports on the treatment of patients with MPHL using dutasteride have been published. In a phase II, 24-week, double-blind, placebo-controlled, dose-ranging study, it was found that dutasteride increased hair growth in a dose-dependent manner.¹² In this study, 0.5 mg of dutasteride was shown to significantly improve hair counts after 12 and 24 weeks compared with baseline and was at least comparable with 5 mg of finasteride. This study also showed that 2.5 mg of dutasteride had slightly greater effect on the rate and extent of hair growth than 0.5 mg of dutasteride in improvement of MPHL.¹² Another randomized study in 17 pairs of identical twin male patients with MPHL

demonstrated that dutasteride at 0.5 mg significantly reduced hair loss progression versus a placebo group.¹⁶ In addition, a woman with androgenetic alopecia was reported to show limited improvement on finasteride but marked improvement on dutasteride.¹⁷

This study confirmed that 0.5 mg of dutasteride is not only more effective than a placebo, but was also well tolerated, and it has a similar safety profile compared with the placebo group. Total and drug-related adverse events during the study were not significantly different between the two groups, and most adverse events were mild. In addition, no significant difference was observed between the two study groups in terms of sexual function.

Sexually related adverse events such as sexual dysfunction occurred in 4.1% (3/73) in the dutasteride group. This frequency was similar to those reported by previous studies of finasteride in MPHL.¹⁵ In a previous study, decreased libido (1/68) and ejaculation disorder (1/68) at 0.5 mg of dutasteride were reported, and a higher incidence of adverse events, such as a decreased libido (9/71), was observed at 2.5 mg of dutasteride.¹² In the 4-year, phase III trial in benign prostatic hyperplasia, 0.5 mg of dutasteride was well tolerated in long-term use.^{11,12} These reports including our data suggest that 0.5 mg of dutasteride treatment is effective and well tolerated in male patients with MPHL.

To our knowledge, this is the first phase III, randomized, double-blind, placebo-controlled clinical trial to assess the efficacy and safety of 0.5 mg of dutasteride for the treatment of male patients with MPHL. This study demonstrated that 0.5 mg of dutasteride improved hair growth, and adverse events in dutasteride and placebo group were not significantly different. Future study will be needed to evaluate the long-term effect of dutasteride treatment in MPHL.

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