

**A Non-Randomized Uncontrolled Clinical Study to  
Determine the  
Efficacy of HairGenesis™, a New Hairloss Treatment for  
AndroGenetic Alopecia (AGA), also known as pattern  
hairloss in men and women**

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### Introduction to pattern hairloss for men and women

Androgenic Alopecia, or pattern hair loss in a man or woman, is an autosomally mediated chronbiologic phenomenon, affects over 40 million men as well as 20 million women in America. To date, there has been no safe, efficacious method of treating and/or reversing the progression of this disorder without presenting known negative side effects.

There have been numerous proposed treatments for baldness, but only a few have provided effective treatment over a wide range of patients, and none have been based on naturally occurring substances. Androgenic Alopecia (AGA) which describes male pattern alopecia, is considered to be a genetically based disorder<sup>2</sup> and commonly characterized by thinning and loss of hair in affected individuals within a given pattern on the scalp of the head.

This hairloss disorder progresses by causing the affected hair follicles to become smaller and correspondingly, the hair becomes finer. Eventually, the fine hairs may be lost and, thus, baldness results in the affected area. Hair has been classified as being of at least two distinct types, terminal and vellus.<sup>3</sup> A vellus hair is short, fine, thin, and non-pigmented, with the bulb of the hair follicle seated superficially in the dermis of the scalp.

Terminal hairs are long, coarse and pigmented, with the bulb of the follicle seated deep in the dermis. During the thinning stage of alopecia, the hairs in the affected area are believed to transform from terminal to vellus. It is this transformation to vellus hairs that is equated to baldness. The core of the phenomenon is associated with structural miniaturization.

## Background

Androgenic Alopecia (AGA) as well as Benign Prostatic Hyperplasia (BPH) are believed to result from a genetic predisposition associated with 5alpha dihydrotestosterone<sup>4</sup>, which is a highly bio-active metabolite of the androgenic hormone testosterone.

Although these disorders are vastly different in physiology and presentation, the etiology of each stems from this specific hormonal metabolism<sup>5</sup>. In developing treatment for AGA, various hormones such as estrogen and other anti androgens have been tested and found unsuitable due to undesirable side effects<sup>6</sup>, such as feminization of male subjects.

Therefore, it would be desirable to find a treatment for AGA that minimizes the use of bio-affecting drugs. It would be expected that natural ingredients will be biologically more friendly to the user and suitable for long term use with minimal side effects.

## Mechanism of Action

This study contemplates the benefit of a natural or organic composition and method of treatment for Androgenic Alopecia (AGA) in order to reduce or arrest the onset of symptomatology associated with this specific disorder. The preferred formulation employs Beta-Sitosterol, saw palmetto berry extract, lecithin, inositol, phosphatidyl choline, niacin, and biotin in orally administered dosages. The method of treatment is administering a dosage of the stated ingredients. In one embodiment, the dosages may be combined in a single soft gel capsule. The preferred quantities of each is as shown in the following

Table 1:

### CAPSULE DOSAGE

INGREDIENT	DOSAGE
Beta Sitosterol	50 mg
Saw Palmetto Berry Extract (Standardized 85% to 95% liposterolic content)	200 mg
Lecithin	50 mg
Inositol	100 mg
Phosphatidyl Choline	25 mg
Niacin	15 mg
Biotin	100 mcg

The preferred dosage is stated with respect to cholestatin 45% Beta Sitosterol. A dosage from 40 mg to 60 mg each twelve hours has been found most effective. According to the capsule formulation of Table 1, a gel capsule containing 50 mg of beta sitosterol is taken twice per day such as each morning and evening. The preferred dosage is stated with respect to an extract of standardized 85 % to 95% liposterolic content. A dosage of from 160 mg to 240 mg each twelve hours has been found most effective. According to the capsule formulation of Table 1, a gel capsule containing 200 mg of standardized saw palmetto extract is taken twice per day such as each morning and each evening.

According to another aspect, the invention provides a means for emulsifying Beta Sitosterol and saw palmetto extract, or an emulsifier system component that aids the other components in penetrating the stomach lining. A suitable emulsifier is lecithin, inositol, or preferably a mixture of both. The preferred dosage of Table I is stated with respect to lecithin consisting of 61-64% phosphatides, for which the dosage is 50 mg each twelve hours. The preferred dosage of inositol is 100 mg each twelve hours. These emulsifier system components can be varied in dosage by a large factor without harm or toxicity.

As means of protecting follicles from degeneration due to oxidation, free radicals and metabolic by-products, the treatment provides an antioxidant component such as phosphatidyl choline. An orally administered dosage of 25 mg per twelve hours provides a general antioxidant prophylactic effect throughout the body.

A vasodilator component is also provided, wherein preferred elements are niacin, biotin, and preferably both. Niacin, or vitamin B3, generally promotes circulation and is beneficial in maintaining and promoting circulation to the follicles. D-Biotin, or vitamin H, compliments the effects of niacin. These dosages are approximate and may be varied by a large factor such as 50% or more.

The shell of a gel capsule may be formed of gelatin, glycerin, water, titanium dioxide, and such other pigments as may be desired. The preferred dosage of Table I provides a suitable quantity of each ingredient for treatment at twelve hour intervals.

In the dosages and treatments, Beta Sitosterol and saw palmetto berry extract are considered the active ingredients. Their disclosed dosage is suitable for achieving effective treatment with intermittent administration approximately at twelve hour intervals. The remaining components are administered in a mixture with the active ingredients for internal administration and may be considered supplemental to enhance the action of the active ingredients.

The formulation is believed to function on a molecular level via competitive mechanical inhibition of the T1 and T2 5-Alpha-DHT cellular and nuclear androgen receptor sites found within susceptible scalp hair follicles. Unbound 5alphaDHT is thus metabolized out of the body via primary excretion pathways without triggering the secondary and pathological cascade of events associated with this disorder.

## Study Overview

The goal of this study is to determine the safety and efficacy of a naturally derived oral formulation (HairGenesis™) containing known anti-androgenic components, in arresting and/or reversing onset of typical Androgenic Alopecia (AGA). Statistical analysis to be determined by gross clinical evaluation, patient reporting, and baseline, intra-study, and end point photographic evidence.

### Treatment Period

Orally, one (1) HairGenesis™ Soft Gel twice a day. Participants to be followed over the course of six months time period. Participants to report to clinic one time per month during this period for follow up investigator evaluation.

### Adverse Events

Any participant adverse event reported during this study to be fully documented per standard protocol parameters.

### Inclusion Parameters

Males and females between the ages of 18 and 55 who are experiencing Androgenetic Alopecia (pattern hair loss in men or women) as determined by the Norwood Class Scale, in a clinical investigator evaluation.

### Exclusion Parameters

- Participants with undetermined reason for hairloss
- Participants using other medications on the scalp
- Participants with no family history of hair loss
- Participants with red, inflamed, infected, irritated or painful scalp
  
- Participants who have been diagnosed with alopecia areata, lupus, erythematosus, or other non-male pattern alopecia / hairloss.

### Clinical Impression Legend

<b>S=SUBJECTIVE</b>	<b>S-1</b>	<b>Follow up evaluation</b>
<b>S-2</b>		<b>Other</b>
<b>O=OBJECTIVE</b>	<b>0-1</b>	<b>Hairloss continuing, no benefit</b>
<b>0-2</b>		<b>Hairloss arrested, no further loss</b>
<b>0-3</b>		<b>Hairloss reversed, noticeable thickening</b>
<b>P=PLAN</b>	<b>P-1</b>	<b>Continuing treatment</b>
<b>P-2</b>		<b>Discontinuing treatment</b>
<b>P-3</b>		<b>Modifying treatment</b>

### Evaluation Analysis

**Incidence and degree of side effects, if any:**

0% of participants reported drug interaction or side effects.

**Incidence and degree of adverse events, If any:**

0% of participants reported any adverse events.

**Reduction in rate of hairloss, If any:**

**100% of participants reported hairloss stopped with no further loss.**

**Aesthetically meaningful change in caliber of affected scalp hair, if any, as evidenced by clinical photography, patient reporting and investigator clinical impression:**

**84% of participants reported hair loss reversed and noticeable thickening of their hair with continued hairloss treatment.**

**Dramatic thickening reported:**

0% of participants reported dramatic thickening.

### Study Synopsis

This research study over a six month period did not reveal any side effects, drug interactions or adverse events. Based on the data gathered, all participants (100%) in the study reported an arresting of symptomatology commonly associated with Androgenic Alopecia and 84% reported an aesthetically meaningful change in the caliber of affected scalp hair.

These findings were determined via investigator observation, baseline, intra study, and endpoint photographic evidence, as well as patient reporting. This study suggests a highly efficacious and safe treatment methodology. Based on these highly positive findings, further study is clearly indicated and presently underway.

### Exhibit A: Clinical Study Statistics with HairGenesis™

Androgenic Alopecia, or pattern hair loss in a man or woman, is an autosomally mediated chronbiologic phenomenon, affects over 40 million men as well as 20 million women in America. To date, there has been no safe, efficacious method of treating and/or reversing the progression of this disorder without presenting known negative side effects.

There have been numerous proposed treatments for baldness, but only a few have provided effective treatment over a wide range of patients, and none have been based on naturally occurring substances. Androgenic Alopecia (AGA) which describes male pattern alopecia, is considered to be a genetically based disorder<sup>2</sup> and commonly characterized by thinning and loss of hair in affected individuals within a given pattern on the scalp of the head.

This hairloss disorder progresses by causing the affected hair follicles to become smaller and correspondingly, the hair becomes finer. Eventually, the fine hairs may be lost and, thus, baldness results in the affected area. Hair has been classified as being of at least two distinct types, terminal and vellus.<sup>3</sup> A vellus hair is short, fine, thin, and non-pigmented, with the bulb of the hair follicle seated superficially in the dermis of the scalp.

Terminal hairs are long, coarse and pigmented, with the bulb of the follicle seated deep in the

dermis. During the thinning stage of alopecia, the hairs in the affected area are believed to transform from terminal to vellus. It is this transformation to vellus hairs that is equated to baldness. The core of the phenomenon is associated with structural miniaturization.

START	NAME	SEX	AGE	FORMULA	CLASS	MONTH #1			MONTH #2			MONTH #3			MONTH #4			MONTH #5			MONTH #6		
						S	O	P	S	O	P	S	O	P	S	O	P	S	O	P	S	O	P
5.19.97	DOUG V	M	35	ORAL	4	1	3	1	1	3	1	1	3	1	1	3	1	1	3	1	1	3	1
5.20.97	MARK H	M	41	ORAL	5	1	3	1	1	3	1	1	3	1	1	3	1	1	3	1	1	3	1
5.30.97	STEVE B	M	37	ORAL	4	1	3	1	1	3	1	1	3	1	1	3	1	1	3	1	1	3	1
6.7.97	MARLIN W	M	38	ORAL	6	1	3	1	1	3	1	1	3	1	1	3	1	1	3	1	1	3	1
6.9.97	TRAVIS R	M	52	ORAL	6	1	3	1	1	3	1	1	3	1	1	3	1	1	3	1	1	3	1
6.20.97	JOYCE K	F	47	ORAL	5	1	2	1	1	3	1	1	3	1	1	3	1	1	3	1	1	3	1
6.26.97	TERRY K	M	38	ORAL	4	1	3	1	1	3	1	1	3	1	1	3	1	1	3	1	1	3	1
6.27.97	KEVIN C	M	37	ORAL	6	1	3	1	1	3	1	1	2	1	1	3	1	1	3	1	1	3	1
6.30.97	RICK B	M	47	ORAL	6	1	3	1	1	3	1	1	3	1	1	3	1	1	3	1	1	3	1
7.14.97	TOM M	M	38	ORAL	7	1	3	1	1	3	1	1	3	1	1	3	1	1	3	1	1	3	1
7.17.97	DAN B	M	38	ORAL	7	1	3	1	1	3	1	1	3	1	1	3	1	1	3	1	1	3	1
7.21.97	LANCE M	M	38	ORAL	5	1	3	1	1	3	1	1	3	1	1	3	1	1	3	1	1	3	1
8.9.97	MARSHALL M	M	34	ORAL	5	1	3	1	1	3	1	1	3	1	1	3	1	1	3	1	1	3	1
9.4.97	JIM M	M	38	ORAL	5A	1	3	1	1	3	1	1	3	1	1	3	1	1	3	1	1	3	1
9.10.97	JOHN W	M	36	ORAL	4	1	3	1	1	3	1	1	3	1	1	3	1	1	3	1	1	3	1
10.7.97	RICK W	M	34	ORAL	3	1	3	1	1	3	1	1	3	1	1	3	1	1	3	1	1	3	1
10.8.97	TED L	M	46	ORAL	3	1	2	1	1	2	3	1	2	3	1	1	1	1	1	1	1	1	1
10.8.97	TOM B	M	45	ORAL	3	1	2	1	1	3	1	1	3	1	1	3	1	1	3	1	1	3	1
10.9.97	JOHN P	M	36	ORAL	4	1	2	1	1	3	1	1	3	1	1	3	1	1	3	1	1	3	1
10.13.97	RICK R	M	37	ORAL	5	1	3	1	1	3	1	1	3	1	1	3	1	1	3	1	1	3	1
11.20.97	STEVE L	M	48	ORAL	5-6	1	3	1	1	3	1	1	3	1	1	3	1	1	3	1	1	3	1
12.3.97	SCOTT S	M	25	ORAL	7	1	2	1	1	3	1	1	3	1	1	3	1	1	3	1	1	3	1
12.18.97	TOM L	M	45	ORAL	6	1	3	1	1	3	1	1	3	1	1	3	1	1	3	1	1	3	1
1.15.98	GARY V	M	43	ORAL	4	1	3	1	1	3	1	1	3	1	1	3	1	1	3	1	1	3	1
2.5.98	DON M	M	51	ORAL	5A	1	3	1	1	3	1	1	3	1	1	3	1	1	3	1	1	3	1

**Exhibit B: Before Use and After Use Photos with HairGenesis™**

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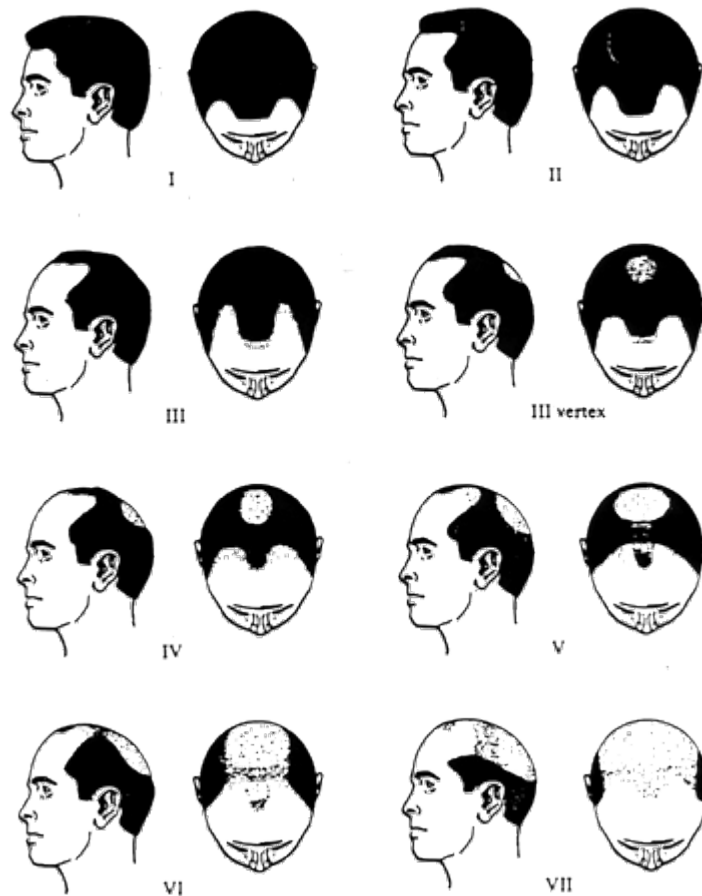
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Exhibit D: Norwood HairLoss Chart



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