



Surgical & Cosmetic Dermatology

ISSN: 1984-5510

ISSN: 1984-8773

Sociedade Brasileira de Dermatologia

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Surgical & Cosmetic Dermatology, vol. 12, núm. 1, 2020, Janeiro-Março, pp. 51-56

Sociedade Brasileira de Dermatologia

DOI: 10.5935/scd1984-8773.20201211503

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Efficacy assessment of hair ampoule containing human hair follicle stem cells in hair loss reduction in women with androgenetic alopecia

Avaliação da eficácia de ampola capilar contendo células-tronco do folículo piloso humano na redução da perda capilar em mulheres acometidas por alopecia androgenética

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ABSTRACT

Introduction: Androgenetic alopecia is characterized by the thinning and progressive hair loss due to the action of androgen hormones, causing the miniaturization of follicles and altering hair cycle.

Objective: To assess the efficacy of a topical hair ampoule containing human follicle stem cells, in women with androgenetic alopecia.

Methods: We used phototrichogram and image analysis to determine investigational product's efficacy compared to placebo after four months of treatment.

Results: There was significant increase in the percentage of anagen hair (34.99%) and a decrease in the percentage of telogen hair (16.59%) for the treated group, what did not occur for the placebo group. There was significant increase in the scalp coverage for the treated participants after four months of product use (33.6%).

Conclusions: The topical investigational treatment was effective to improve hair loss in female androgenetic alopecia after four months of treatment.

Keywords: Alopecia; Hair; Clinical Trial; Hair Preparations

RESUMO

Introdução: A alopecia androgenética caracteriza-se pelo afinamento e perda progressiva dos fios de cabelo decorrentes da ação dos hormônios andrógenos, causando a miniaturização dos folículos e diminuição do tempo de duração do ciclo capilar.

Objetivo: Avaliar a eficácia de ampola tópica capilar contendo células-tronco do folículo piloso humano em mulheres com alopecia androgenética.

Métodos: Utilizou-se fototricograma e método de análise de imagem por cobertura para determinar a eficácia do produto investigacional comparado ao placebo após quatro meses de tratamento.

Resultados: Houve aumento significativo no percentual de fios anágenos (34,99%) e redução no percentual de fios telógenos (16,59%) para o grupo tratado, o que não ocorreu no grupo placebo. Houve aumento significativo na cobertura do couro cabeludo das participantes tratadas após quatro meses de uso do produto (33,6%).

Conclusões: O tratamento tópico investigacional foi eficaz na melhora da perda capilar da alopecia androgenética feminina após quatro meses de tratamento.

Palavras-chave: Alopecia; Cabelo; Ensaio clínico; Preparações para cabelo

Artigo Original

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Received on: 16/12/2019

Approved on: 10/03/2020

Study conducted at the Instituto de Pesquisa Clínica Integrada Ltda, Jundiaí, SP, Brazil.

Financial support: Lupin Farmacêutica.

Conflict of interests: None.



INTRODUCTION

Androgenic alopecia is among the most common causes of hair loss and among the main complaints by patients in the physician's office. It is characterized by miniaturization of hair follicles and alteration of the hair cycle resulting from action by androgen hormones, with shortening of the anagen phase and lengthening of the telogen phase.^{1,2}

Various methods can be employed in the diagnosis of abnormalities in the hair growth cycle, as well as in the evaluation of treatment efficacy. Such methods feature phototrichogram and imaging analysis with macrophotography.³ Phototrichogram is a non-invasive method in which the hair is cut close on the test region and an image is taken two to three days later for determination of the amount of hairs in the anagen and telogen phases.²⁻⁵

Macrophotography is used for the capture and comparison of paired images before and after treatment for verification of improvement in hair growth. The analysis requires standardization of the capture conditions and the patient's hair grooming in each moment.³ The images obtained can be evaluated both visually and by scalp coverage image analysis software.⁶

The current study aimed to investigate the effect of topical treatment with Recrexina® on the improvement of hair loss in female patients with androgenic alopecia, using phototrichogram Dermoscope Dynamic® with Trichoscale® software (FotoFinder Systems GmbH, Bad Birnbach, Germany) and image analysis with macrophotography.

Ethical aspects:

The current study was conducted after ethical approval of the dossier (CAAE: 08929219.1.0000.5386). All participants were oriented on the study protocol and had their questions answered prior to signing the free and informed consent form. All participants gave their consent before being included in the study.

METHODS

Study design

The current clinical trial was prospective, randomized, placebo-controlled, and single-blind.

Participants' inclusion and study site

An invitation was issued to appear at the IPclin Instituto de Pesquisa Clínica Integrada Ltda. (Jundiaí-SP) to 51 female participants presenting androgenic alopecia, ranging in age from 30 to 50 years, with Fitzpatrick skin types I to IV, and who met the inclusion criteria specified in the study protocol.

The inclusion criteria were: age 30 to 50 years; female gender; complaint of hair loss; diagnosis of androgenic alopecia; habit of washing hair at least three times a week; good health status; intact skin on the scalp; Fitzpatrick skin types I to IV; no self-reported risk of becoming pregnant during the study.

The following exclusion criteria were used during the selection process for participants: use of hair appliques; pregnancy or breastfeeding; cicatricial alopecia; immunodeficiencies; active atopic dermatitis; kidney, heart or liver transplant patients; sunburn on the study area resulting from intense solar exposure within a month before the study; use of corticoids, antihistamines, immunosuppressants, retinoids, or anti-inflammatory drugs; other concurrent diseases of the scalp, such as infections, psoriasis, and important seborrheic dermatitis; prior hair transplant or scalp reduction surgery; use of hair extenders or wigs in the last three months; use of minoxidil or finasteride (oral or topical) in the last six months; treatments with low-energy infrared or laser in the last six months; curl softening in the three months prior to the study.

Individuals that consented to participate in the trial underwent the initial dermatologic examination for diagnosis of androgenic alopecia and verification of the inclusion and exclusion criteria, having been divided randomly into two groups (treated versus placebo). They then underwent the phototrichogram examination and had standardized photographs taken with a professional camera (Canon® t3i).

Patient Treatment

After collection of the baseline data, treatment was dispensed to the participants for four months of home use. Patients were instructed to use the investigational product on their clean, dry scalp once a day, massaging it in, from Monday through Friday. Half received the placebo treatment and the other half received the treatment with the study product, according to single-blind randomization.

The investigational product was a topical treatment with human hair follicle stem cells, containing a combination of patented active ingredients, with the brand name Recrexina® Human Follicle Stem Cells - HFSC 100% (Regrowth), (patented by Laboratório Lupin - Medquímica - Juiz de Fora, MG, Brazil).

Phototrichogram analysis

For the phototrichogram analysis, the site was selected on the frontoparietal region for standardized close-cut of hairs on an area of 2cm². Participants then appeared again two days later for capturing the photographic image of the hairs with the Dermoscope Dynamic® (FotoFinder Systems, Inc., Maryland, USA), using 20X magnification. This procedure was performed before the treatment (baseline visit) and was repeated 120 days after use of the investigational product. In both visits, the analysis was performed in the same region.

At the end, the Trichoscale® software (DermoScan GmbH, Regensburg, Germany) was used to analyze the images with determination of the total number of hairs and the percentage of anagen and telogen hairs. The software performs semiautomatic analysis of the target region.

Analysis of images

Ten participants were selected from the group treated with the investigational product to conduct an evaluation of the efficacy of scalp coverage via macrophotography with subsequent image analysis.

Standardized images were captured from the selected patients before and after the treatment, in the central hair loss region, using a professional camera (Canon® t3i). The captured images were analyzed with the Pro Premier® software (Media Cybernetics, Rockville, USA) to compare the total area of hair loss between the two test times. The analysis was performed as described by Bloch, Escudeiro, and Sarruf (2018).⁶

Statistical analysis

The treatments were compared between the test times via evaluation of the results obtained with the phototrichogram, using the Student's t-test and processed with SPSS version 22.0. Results of the image analysis (scalp area) were compared between the test times using the paired t-test.

RESULTS

Of the 51 participants included in the trial, 26 were allocated to the treatment arm and 25 to the placebo arm. Of these, 37 concluded the study (20 in the treatment arm and 17 in the placebo arm). The other participants dropped out for personal reasons. Of the 20 participants who concluded the study in the treatment arm, 10 reported mild initial discomfort with use of the product. According to the warnings on the product insert, effects such as redness and temporary heat reaction (generally interpreted by patients as a burning sensation) are expected. Table 1 lists patients' reports of discomfort. According to the phototri-

TABLE 1: SENSATIONS OF DISCOMFORT REPORTED BY PARTICIPANTS AFTER FOUR MONTHS OF PRODUCT USE (TREATED GROUP)

Participant's number	Reported sensation
3	Mild burning on posterior scalp with all applications
6	Mild burning right after applications
8	Mild burning right after applications
17	Mild burning after the first application
20	Intense burning on scalp
25	Mild burning after some applications
29	Intense burning with the first three applications
31	When washing hair, the water makes the face red, and burning sensation on ears with all applications
42	When washing hair, the rinse water leaves red streaks on face
51	When washing hair, the rinse water leaves red streaks on face

chogram analyses, there was a 6.35% mean increase in the total number of hairs between the two test times (before and after treatment) with the investigational product, and a decrease of 6.63% in hairs with the placebo. However, there was no statistically significant difference in the total number of hairs between the two treatments after four months of use.

There was a mean reduction of 16.59% in telogen hairs between the two times with the investigational product, compared to a 23.89% increase in the placebo group, with a statistical difference between the two arms (p-value = 0.010).

The investigational product was associated with a 34.99% increase in anagen hairs after four months, compared to a 29.42% reduction in the placebo group, with a statistically significant difference between the groups for this parameter (p-value = 0.005).

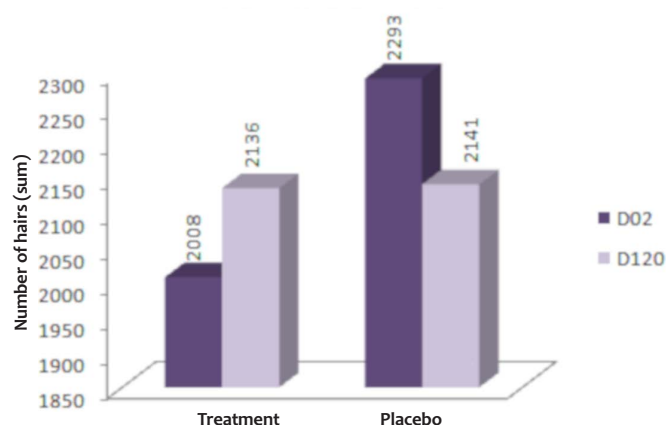
Figure 1 shows the total number of hairs (sum) at each test time according to the study arm. Table 2 summarizes the phototrichogram results. Figures 2 and 3 show the initial and final phototrichogram images of two patients treated with the investigational product.

The analysis of macrophotography images used the Image Pro Premier® software to determine the bare scalp area at each test time, based on the method published by Bloch, Escudeiro, and Sarruf (2018)⁶, for ten participants in the investigational arm.

Figures 4 and 5 show the image analysis of patients treated with the investigational product (before and after). The areas highlighted in red are the bare regions of the scalp. Figure 6 shows the mean bare scalp areas in pixels² at each test time.

The results show a statistically significant improvement in scalp coverage with four months of the investi-

PHOTOTRICHOGRAM – TOTAL NUMBER OF HAIRS



Key: D02 – analysis before treatment; D122 – analysis after treatment.

FIGURE 1: Total number of hairs before and after treatment according to treatment arm

gational product (p -value = 0.013), with a mean reduction of 33.6% in the bare scalp area. This result proves the efficacy of treatment with the investigational product in promoting new hair growth.

DISCUSSION

We can infer from the results that the investigational product provided significant improvement in the patients' androgenic alopecia, with an increase in the percentage of anagen phase hairs (growth) and a reduction in the percentage of telogen hairs (resting phase) after four months of treatment, compared to the placebo group.

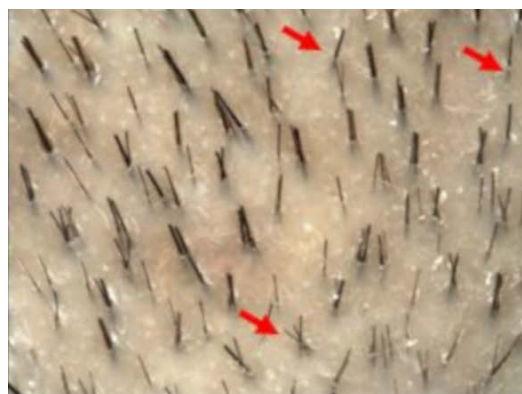
Topical treatment with human hair follicle stem cells has the following mechanisms of action: (1) activation and preservation of bulge stem cells; (2) vasodilatation of the scalp, leading to increased blood flow to the scalp; (3) supply of essential nutrients for hair growth such as amino acids and plant extracts; (4) reduction in activity of the 5α -reductase enzyme (related to balding); and (5) enhancement of capillary keratinization, strengthening the hair.⁷

The investigational product's composition and its mechanism of action corroborate the clinical tests' findings, proving the product's good acceptance and effectiveness for prescription to patients with androgenic alopecia.

TABLE 2: SUMMARY OF PHOTOTRICHOGRAM RESULTS

Group		Total number of hairs		Telogen hairs		% telogen hairs		Anagen hairs		% anagen hairs	
		Before	After	Before	After	Before	After	Before	After	Before	After
Treated	Mean	100,4	106,8	55,5	46,3	53,3	42,4	44,8	60,5	46,6	57,6
	Sum	2008	2136	1110	926	/	/	896	1210	/	/
	Difference	/	128	/	-184	/	/	/	314	/	/
Placebo	Mean	134,9	125,9	56,1	69,4	41,1	55,0	79,1	55,8	59,1	44,4
	Sum	2293	2141	953	1181	/	/	1344	949	/	/
	Difference	/	-152	/	228	/	/	/	-395	/	/

Key: % = percentage; "before" treatment; "after" four months of treatment

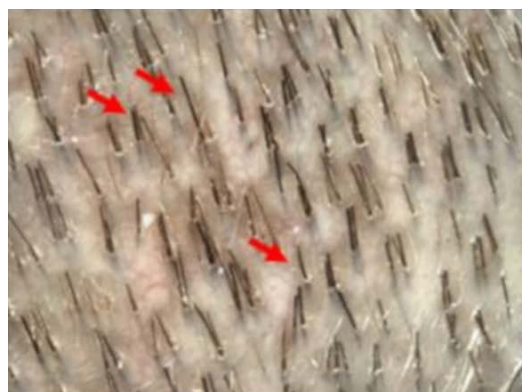


Participant 10 -D02 (Phototrichogram before)

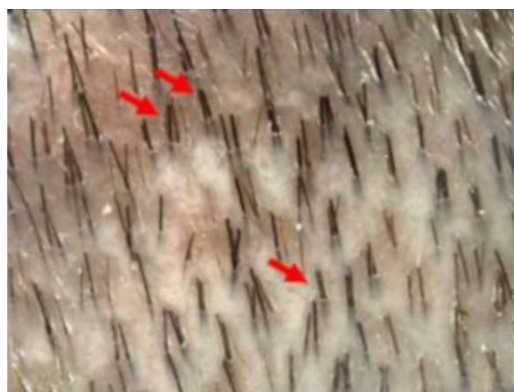


Participant 10 -D122 (Phototrichogram after)

FIGURE 2: Image of phototrichogram analysis before and after in patients in treated group (participant reference number: 10). Arrows indicate increase in quantity of hairs.



Participant 47 -D02 (Phototrichogram before)



Participant 47 -D122 (Phototrichogram after)

FIGURE 3: Image of phototrichogram analysis before and after in patients in treated group (participant reference number: 47). Arrows indicate increase in quantity of hairs.

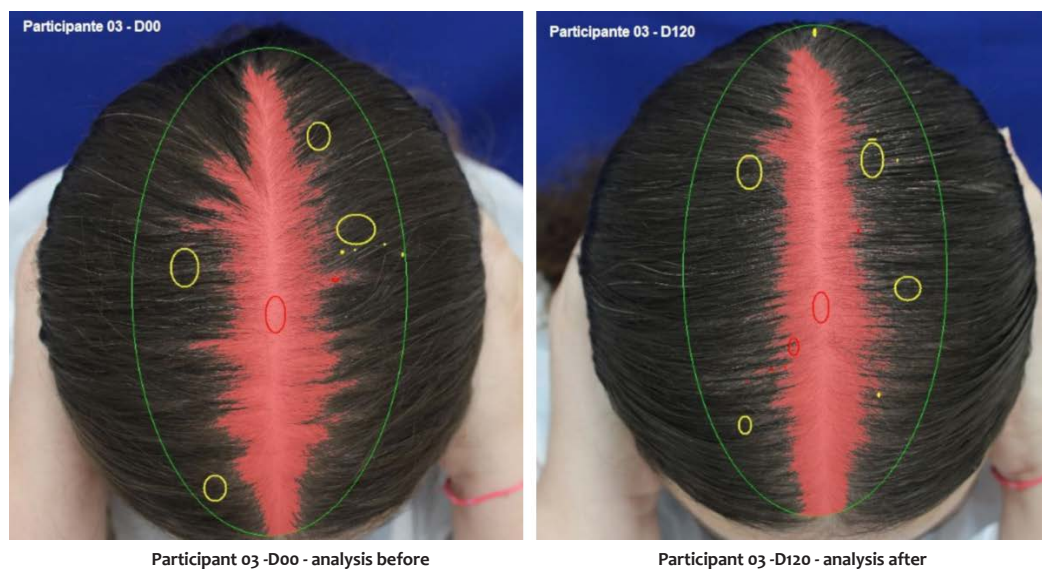


FIGURE 4: Result of before and after analysis (participant reference number: 03). Participant 03; area on D00 = 121821; area on D120 = 62245; Improvement: 49%

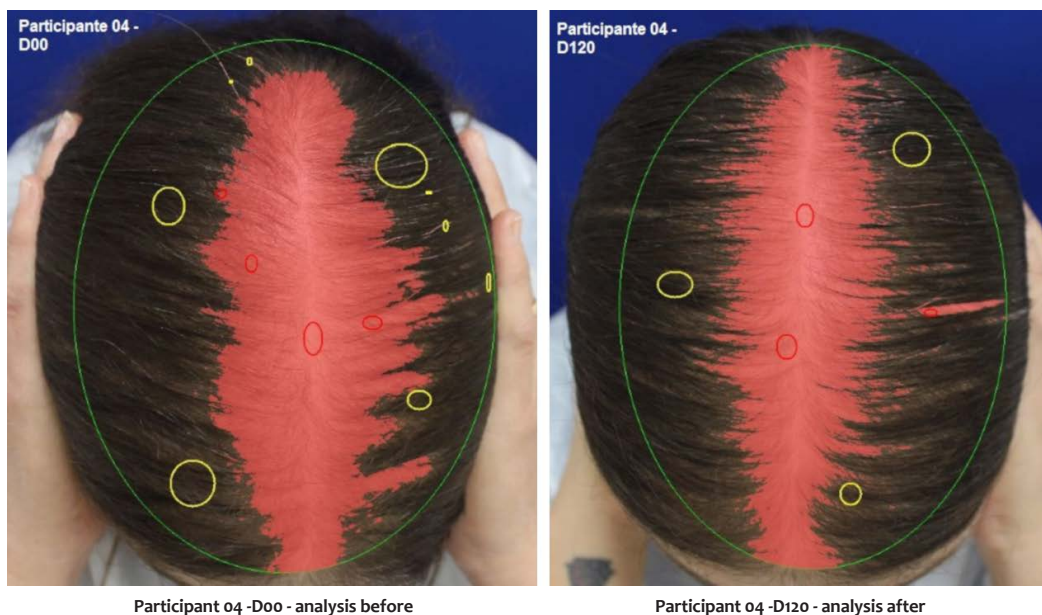
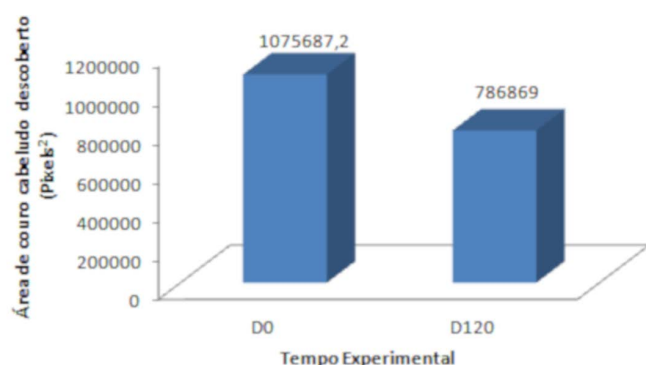


FIGURE 5: Result of before and after analysis (participant reference number: 04). Participant 04; area on D00 = 813496; area on D120 = 77429; Improvement: 90%

ANÁLISE DE IMAGEM



Key: D00 – analysis before; D120 – analysis after

FIGURA 6: Result of before and after image analysis – mean area of uncovered scalp (Pixels²)

CONCLUSION

The product containing human hair follicle stem cells was effective after four months of treatment in patients with androgenic alopecia, when compared to placebo, based on analyses of hair loss with images and phototrichogram, proving to be a treatment with excellent potential.

The investigational treatment led to a 16.59% mean reduction in telogen hairs, a 34.99% mean increase in anagen hairs, and 33.6% mean increase in scalp coverage. ●

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Critical revision of the manuscript.