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Study Objectives:

To investigate the efficacy and tolerance of Hair Activator Solutions, active 7% MKMS24, in the treatment of non-scarring diffuse alopecia areas using non-invasive technologies in treating hair loss.

Study Design

This was a randomized, blinded, intra-individual comparative cosmetic study. A total of 30 subjects participated in the clinical trial that was conducted at the University Clinic in Chile. The study started in September and ended in November 2018 with a duration of 90 days.

Background

Hair loss can occur at any age, although it is more common in people aged 15 to 29. Approximately 30 to 40% of women experience hair loss. Men are considerably more affected by hair loss. Statistically 70% of men experience this issue.

In this clinical trial, the investigators aim to confirm the efficacy and tolerance of Hair Activator Solutions, active 7% MKMS24, in the treatment of non-scarring diffuse alopecia areas using non-invasive technologies in treating hair loss. Hair Activator Solution contains active 7% MMS24, a unique anti-hair loss active that is based on Lentil, Thyme and Bamboo. MKMS24 strongly stimulates the dermal papilla to produce fibroblast growth factor 7 (FGF7) and the Nogin protein. Nogin has an indirect function, inhibiting the activity of bone morphogenetic protein 4 (BMP4), with a suppressive role in the transition from the Telogen phase to the Anagen. FGF7 directly stimulates the dermal papilla to start a new hair cycle. MKMS24 also acts by inhibiting 5 alpha reductases.

Patients and Methods

The subjects were 30 voluntary patients with diffuse non-scarring alipecia of a public hospital as well as a private clinic in Santiago de Chile. In the last 90 days, the volunteers did not have previous treatments to confirm the clinical efficacy of the treatment based on Hair Activator Solutions, active 7% MKMS24. Patients applied the product twice a day, morning, and evening, according to the manufacturer's instructions for a period of 12 weeks.
In addition, the study assessed the number of hair follicles at different stages of the hair growth cycle using non-invasive technologies and evaluated the properties of Hair Activator Solutions, with the questionnaire being voluntary. The parameters to be studied were evaluated through clinical examinations, instrumental methods and a questionnaire applied by professionals. The aim of the questionnaire was, on the one hand, the subjective assessment of the product respectively cosmetic acceptance of the formulation and, on the other hand, the subjective evaluation of the product efficacy

(increase in capillary volume). During the study period, adverse reactions such as burning, itching, and peeling, as well as possible contraindication to the product were evaluated. Also, no additional hair growth hormones or silicone shampoo were used during this time frame.
The selected patients of the study had to fulfil the following characteristics:

- Volunteers diagnosed with non-scarred diffuse alopecia,
- Age between 20 and 65 years,
- No change in hormone therapy during the last 90 days or during the study,
- No topical or systemic treatments at the beginning of the study and/or 90 days before,
- No history of intolerance to topical products, and
- Signing of informed consent.

The study excluded patients with at least one of the following traits:

- Pregnancy or lactation,
- Current treatment for alopecia or during the last 6 months,
- Diagnosis of cicatricial alopecia,
- Anagen effluvium,
- History of allergic reactions to the product, which is used, or
- Systemic, cutaneous pathology or any medication that may alter the parameters to be evaluated.

The patients were evaluated on Day 0, Day 45, and Day 90. First, the type of alopecia was clinically diagnosed. This was achieved by looking at the clinical history, carrying out a physical examination and, if necessary, conducting laboratory tests (hematologic, ferremia, thyroid profile). Also, a digital photography and conventional trichogram were taken.
The products were delivered with the manufacturer's instructions and a standard shampoo was provided. It was instructed to issue a warning if any complaints arose and not to use any products that interact with the study (anti-hair loss shampoo, other treatments for hair loss etc.).

Results

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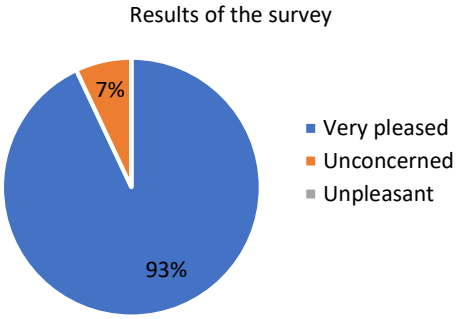
Statistical Analysis



The programme "stata v.14" was used to analyse the statistical data. The distribution of the recorded data was analysed with the Shapiro Wilk test, which does not follow a normal distribution. To determine if there was an association between the variables, the Wilcoxon (for paired samples), Xi2 and Mann-Whitney test were used. In summary, 25 patients have completed the study. In total, there were 9 women (36%) and 16 men (64%), with the average age of the sample being 36.2 years.
After 90 days of treatment patients have a significantly higher anagen trichogram, p<0.001, and a significantly lower telogen trichogram, p<0.001.

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. sum TricogramaD0anageno TricogramaD90anágeno
```

Variable	Obs	Mean	Std. Dev.	Min	Max
Tricog~ageno	25	79.28	9.910096	50	94
Tricog~ágeno	25	89.12	3.811386	80	94

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.
. sum tricogramaD0telógeno TricogramaD90telogeno
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Variable	Obs	Mean	Std. Dev.	Min	Max
tricograma~o	25	20.64	9.886354	6	50
Tricog~ogeno	25	10.88	3.811386	6	20

On the scale measured, the average quality of life was less than 90 days. Thus, after 90 days of treatment, patients had a significantly lower quality of life score, p = 0.004, which translates into an improvement in quality of life according to the DLQI.

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. sum PuntajecalidaddevidaCVD0 PUNTAJECVD90
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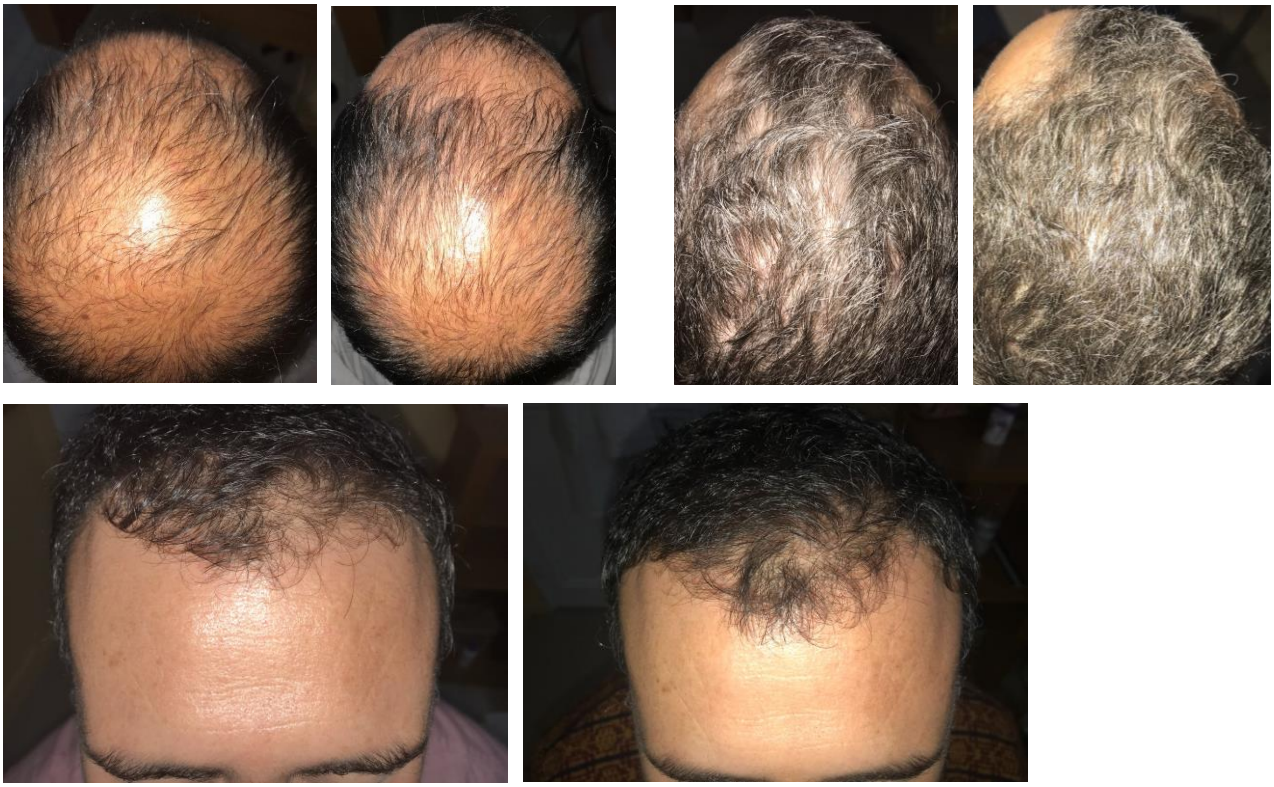
Variable	Obs	Mean	Std. Dev.	Min	Max
Puntajecal~0	25	2	2.533114	0	9
PUNTAJECVD90	25	.52	.8717798	0	3

In summary, 93% of patients were very satisfied with Hair Activator Solutions. Furthermore, none of the patients experienced the product as unpleasant, as shown in the graph. 85% of the patients noticed improvements, 81% of the patients noticed increased hair density, 66% of patients noticed a decrease in hair loss, and a better overall appearance of their hair. Also, 85% of the patients would recommend Hair Activator Solutions and 97% of the patients would continue using the product.

None of the results presented above were associated with treatment response. Also, the response to the treatment was independent of the sex and age of the patient. There were no adverse effects associated with the use of the product.

The clinical photos from day 0 compared to day 90 are shown below:



The patients who used the Hair Activator Solutions showed statistically significant improvement in the trichogram, with an increase in anagen hairs and decrease a decrease in telogen hairs. This corresponded to the patients' perception of improvement in the appearance, volume-density, and decrease in hair loss. Also, the cosmetics aspect of the product was accepted by most patients. Most patients would continue to use the product and recommend its use.

Conclusions

In this clinical trial, the investigators confirm the significant efficacy and tolerance of Hair Activator MKMS24.