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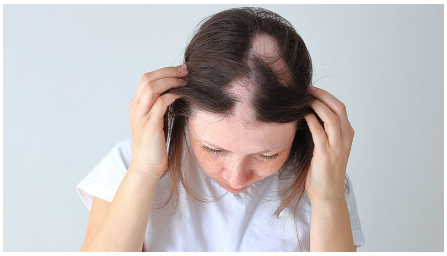

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Topical Botanical Drug Coacillium Curbs Childhood Alopecia

Sara Freeman

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Considerable hair regrowth can be achieved in children with alopecia areata with the use of a novel plant-based drug, according to research presented during the first late-breaking news session at the annual meeting of the European Academy of Dermatology and Venereology.

In the RAAINBOW study, a greater mean relative improvement in the Severity of Alopecia Tool (SALT) scores at 24 weeks was recorded in children who had been treated topically with coacillium (22.9%) than in those who had received a topical placebo (-8.0%), with a significant 31% overall difference ($P < .0001$).

"Coacillium cutaneous solution was used for the first time for treatment of alopecia areata and also for the first time used in a pediatric population," the presenting investigator Ulrike Blume-Peytavi, MD, said at the meeting.

"It's well tolerated, and in fact what is interesting is, it has a durable response, even after treatment discontinuation," added Blume-Peytavi, who is the deputy head of the Department of Dermatology, Venerology and Allergology at Charité-Universitätsmedizin Berlin in Germany.

Backing the Botanical?

Paola Pasquali, MD, a dermatologist at Pius Hospital de Valls in Spain, who co-chaired the session where the findings were presented, commented, "Thank you for showing that chocolate is great! I knew it. It is fantastic to see how chocolate is used."

Pasquali was referring to the coacillium ingredient *Theobroma cacao* extract. The seeds of *T cacao*, or the cocoa tree, are used to make various types of chocolate products. *Theobroma cacao* is one of four plant extracts that make up coacillium, the others being *Allium cepa* (onion), *Citrus limon* (lemon), and *Paullinia cupana* (guaraná, a source of caffeine).

The four plant extracts are classified as "generally regarded as safe" (GRAS), Blume-Peytavi observed, noting that the development of coacillium fell under the category of a prescription botanical drug as set out by the US Food and Drug Administration or a herbal medicinal product as set out by the European Medicines Agency.

But How Does It Work?

The botanical's mode of action of acting positively on hair follicle cycling and endothelial cell activation was called into question, however, by Emma Guttman-Yassky, MD, PhD, who was in the audience.

She asked, "So how do you explain that, after three large studies with topical JAK inhibitors that did not work actually in alopecia areata because it's very hard to penetrate the scalp for a topical [drug], this one works?"

Guttman-Yassky, professor of dermatology and immunology at the Icahn School of Medicine at Mount Sinai, New York City, added: "Looking at the ingredients, to me, it seems that it's more like a DPCP [diphenylcyclopropenone]-like reaction."

DPCP, which has been used to treat alopecia, purportedly works by stimulating the immune response to target the skin surface — causing an allergic reaction — rather than the hair follicle.

It's an interesting question as to how a molecule penetrates the hair follicle, and it depends on the size of the molecule, Blume-Peytavi responded.

"We have done a lot of studies on follicular penetration, and we are quite aware that you need a certain size of the molecule," she said. Between 14 and 200 nanometers appears to produce "the best penetrators," she observed.

Blume-Peytavi commented that even after topical JAK inhibitors are applied, the molecules that penetrate do not remain in the local area for very long, yet still produce an inhibitory signaling effect.

No scalp irritation was seen in the trial, which suggests that coacillium is not working in the same way as DPCP, Blume-Peytavi countered.

Evaluating Efficacy and Safety: The RAAINBOW Study

Blume-Peytavi acknowledged that JAK inhibitors were "a tremendous advance in treating severe and very severe alopecia areata," but because of their benefit-to-risk ratio, there was still an unmet need for new treatments, particularly in children, in

whom drug safety is of critical importance.

Having a drug that could be given safely and also have an effect early on in the disease, while it is still at a mild to moderate stage, would be of considerable value, Blume-Peytavi maintained.

The RAAINBOW study was a randomized, double-blind, phase 2/3 trial conducted at 12 sites in Germany and three other countries between March 2018 and March 2022 to evaluate the efficacy and safety of coacillium in the treatment of children and adolescents with moderate to severe alopecia areata.

In all, 62 children aged 2-18 years (mean age, 11 years) participated; 42 were treated twice daily with coacillium cutaneous solution 22.5% and 20 received placebo for 24 weeks. Treatment was then stopped, and participants followed for another 24 weeks off treatment to check for disease relapse, bringing the total study duration up to 48 weeks.

Baseline characteristics were "relatively comparable for severity," Blume-Peytavi said. Most of the children had severe alopecia areata (57% for coacillium and 65% for placebo); the remainder had moderate disease (43% vs 35%, respectively).

The average SALT scores at the start of treatment were 56 in the coacillium group and 62 in the placebo group, and a respective 44 and 61 at the end of 24 weeks' treatment.

Perhaps the most important results, Blume-Peytavi said, was that at 48 weeks of follow-up, which was 24 weeks after treatment had been discontinued, the mean SALT scores were 29 for coacillium and 56 for placebo ($P < .0001$).

"You can see the improvement in the treated group is continuing even without treatment. However, the placebo group stays relatively about the same range," she said.

Overall, 82% of patients treated with coacillium and 37% of those who received placebo experienced hair growth after treatment had stopped, and by week 48, a respective 46.7% vs 9.1% had a SALT score of 20 or less, and 30.0% vs 0% had a SALT score of 10 or less.

No safety concerns were raised, with no serious treatment-related reactions, no immunosuppressant-like reactions, and no steroid-like side effects.

Beyond the RAAINBOW

Larger studies are needed, Blume-Peytavi said. According to developer Legacy Healthcare's website, coacillium cutaneous solution is not just being developed for

childhood alopecia areata. It is also under investigation as a treatment for persistent chemotherapy-induced alopecia, atopic dermatitis, and psoriasis. In addition, an oral solution is being tested for cancer-related fatigue.

The study was funded by Legacy Healthcare. Blume-Peytavi has received research funding and acts as an advisor to the company, among others; four of the study's coauthors are employees of the company. Pasquali and Guttman-Yassky were not involved in the study and had no relevant financial ties to disclose.

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