Modulation of FOXP3 Expression and Regulatory T-Cell Activity by Gum Rosin-Modified Ointment: A Multi-Phase Preclinical and Clinical Study for Psoriasis Treatment

Badran, Ibrahim (School: Dakahlia STEM School)

Psoriasis silently torments 125 million people worldwide, yet current therapies such as corticosteroids and biologics thin the skin, suppress the immune system, and lose efficacy over time, while neither addresses the disease's immunological root. The 2025 Nobel Prize in Physiology or Medicine validated FOXP3+ Regulatory T-cells (Tregs) as master regulator of immune tolerance. A pathway that is critically deficient in psoriasis, exposing a precise therapeutic target for psoriasis. This study engineered Rosiderm: a topical ointment of gum rosin, a natural pine resin rich in abietic and dehydroabietic acid, targeting both immune dysregulation and epidermal hyperproliferation simultaneously. Across 3 rigorously controlled studies, safety, efficacy and stability of Rosiderm were validated. First, in-vivo study was done with a 36-rabbit imiquimod-induced psoriasis model, Rosiderm achieved 88% severity reduction versus 48% for the betamethasone-salicylic acid standard, a 184% faster recovery ($p<0.0001$; Cohen's $d=0.84$). Immunohistochemistry confirmed marked FOXP3+ Treg upregulation. Second, Phase I dose-escalation human trial (n=40, 8/group) demonstrated dose-proportional systemic absorption across all cohorts ($R^2=0.978$), with Cmax ranges from 0.22 ± 0.05 to 0.63 ± 0.18 ng/mL across the 5–20% concentrations. No severe adverse events recorded. Third, phase II double-blinded human trial (n=125, 25/group) showed Rosiderm achieving 90% severity reduction, with PASI-75 response in 21 of 25 patients, significantly outperforming the standard betamethasone ($p<0.001$). The formulation physical stability was confirmed across 8 months. Together, these findings establish Rosiderm as a safe, affordable and efficacious alternative to existing therapies for millions of patients globally.

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