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In Vitro Evaluation of Naltrexone HCl 1% Topical Cream in XemaTop™ for Psoriasis

Citation

Ip K., Song G, Banov D, Bassani AS, and Valdez BC. *Archives of Dermatological Research*. 2019 Oct 30. doi: 10.1007/s00403-019-01981-2.

Abstract available at: https://doi.org/10.1007/s00403-019-01981-2

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Issue:

First Online: 30 October 2019

Abstract:

Psoriasis is a multifactorial skin disease involving abnormal cell proliferation and inflammation; an efficacious topical treatment is yet to be identified. A formulation containing 1% Naltrexone HCl in XemaTop™ base was compounded, characterized and evaluated in vitro as a possible treatment for psoriasis. A three-dimensional psoriasis tissue model was exposed to the formulation for 2 or 5 days and analyzed for the level of markers of cellular proliferation, and inflammatory cytokine IL-6. Using immunohistochemical staining, the level of Ki67 protein significantly decreased in the drug-treated tissues. Western blot analysis showed 86% and 53% down-regulation of other proliferation markers PCNA and CYCLIN D1, respectively, after 5-day exposure. The pro-survival Wnt/β-catenin pathway was compromised as indicated by 57% decrease in the level of β-CATENIN and down-regulation of its down-stream targets including CYCLIN D1 (decreased by 53%), c-MYC (63%), c-JUN (92%) and MET (96%) proteins. Likewise, the PI3K/AKT/mTOR pathway was significantly inhibited by 1% Naltrexone HCl in XemaTop™, suggesting protein synthesis was affected. The production of IL-6 was inhibited by 70% in drug-treated tissues. These results suggest that the compounded drug is efficacious in down-regulating molecular markers associated with the pathogenesis of psoriasis. Low-dose Naltrexone in XemaTop™ was stable within 180 days when stored under refrigerated or ambient conditions. These results provide a basis for a clinical evaluation of 1% Naltrexone HCl in XemaTop™ in psoriasis patients.

Related Keywords:

Compounded medication, psoriasis, naltrexone, XemaTop™