Diacerein cream: basal pharmacology and clinical application

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EBS is a rare genetic, blistering skin disease for which there is no cure. Treatments that address the pathophysiology of EBS, with an acceptable safety profile, are needed. We conducted a randomized-controlled phase 2/3 trial of topical application of 1% diacerein cream to treat defined body surface areas in 17 EBS patients. A 4-weeks intervention phase, with the primary endpoint being a reduction in blister numbers >40%, and a 3-months follow-up were conducted in two subsequent years, with a cross-over of groups after year 1. Reaching initial blister numbers (+/-10%) was assessed as secondary endpoint. For patients on diacerein, 86% of patients in treatment period 1 and 37.5% in period 2 achieved a reduction in blister number of >40% after 4 weeks. For patients on placebo, in period 1 14% of patients and 17% in period 2 achieved this outcome. This effect was still significant after the follow-up. Pharmacokinetic analysis of rhein was performed in 2 patients. The highest level of rhein in urine or serum was 39.9 ng/mL and 20.1 ng/mL, respectively. No treatment-related adverse effects were observed. This trial provides evidence of the efficacy and safety of 1% diacerein cream in the treatment of EBS.

Key references:

Wally V, Lettner T, Peking P, et al. The pathogenetic role of IL-1beta in severe epidermolysis bullosa simplex. *J Invest Dermatol* 2013; **133**: 1901-3.

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