

An International, Multicenter, Randomized, Double-Blind, Parallel Group, Vehicle-Controlled, Phase 2/3 Study with Open-Label Extension Evaluating the Efficacy and Safety of Diacerein 1% Ointment for the Treatment of Generalized Epidermolysis Bullosa Simplex (EBS) (AC-203-EBS-007 study)

Study Highlights

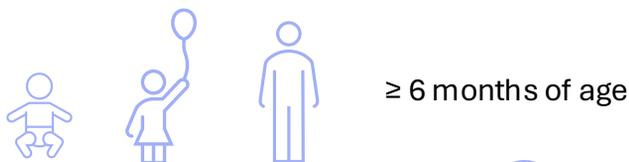
The AC-203-EBS-007 study is an international clinical trial. Participants will be randomized in a double-blind design, in one of two parallel-groups in this Phase 2/3 clinical trial. Researchers will compare the efficacy of diacerein 1% ointment (AC-203) to a control ointment when applied once-daily for eight weeks in people living with EBS. Participants will report outcomes including pain, pruritus, and QOLEB at each visit. In the 24-week extension period, all participants will receive diacerein ointment.

Global Enrollment Number: 80-100 participants

Study Drug: Diacerein 1% ointment (AC-203) or vehicle

We are looking for patients with **Epidermolysis Bullosa Simplex (EBS)** to join our study.

Inclusion criteria (You must have...)



Clinically diagnosed severe EBS or intermediate EBS



Autosomal dominant *KRT5* or *KRT14* gene mutation

EBS lesions ≥ 3% body surface area (BSA)



Treatment area IGA score ≥ 3

Exclusion criteria (You must not have...)

Other clinically significant skin disease(s)



Current cancer or a history of treatment for a cancer within 5 years

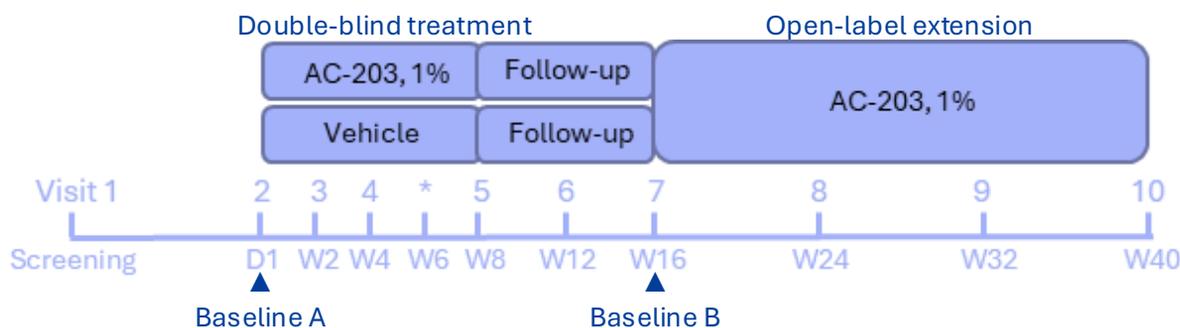


Pregnant or breastfeeding /lactating



Note: If you would like to clarify whether you meet the criteria, please consult your doctor.

Study design: You will be in this study for up to 44 weeks.



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