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) (EBShield Study/AC-203-EBS-007)

Study Overview

The AC-203-EBS-007 study is an international clinical trial for people with Epidermolysis Bullosa Simplex (EBS). Participants will be randomly assigned to use either diacerein 1% ointment (AC-203) or a control ointment once daily for 8 weeks, without knowing which ointment they are using. After an additional 8-week period without treatment, all participants will use diacerein 1% ointment (AC-203) for 24 weeks. Participants will report outcomes, including pain, itching, and quality of life at each visit.

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…)

At least 6 months of age

Clinically diagnosed severe EBS or intermediate EBS

Autosomal dominant *KRT5* or *KRT14* gene mutation

EBS lesions at least 5% body surface area (BSA)

Treatment area IGA score at least 3

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

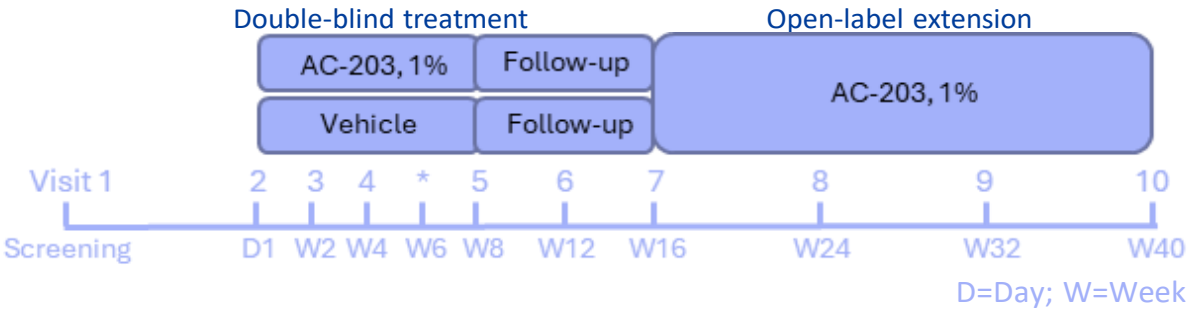
Exclusion criteria (You must not have…)

Other clinically significant skin disease(s)

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

Pregnant or breastfeeding /lactating

Study design: You will be in this study for up to 50 weeks(screening period up to 10 weeks).



Sydney Children's Hospital Randwick
SCHN-SCHClinicaltrials@health.nsw.gov.au

A/Prof Artiene Tatian
(02) 9382 5534

AUS Version 1.1_30Jul2024
SCH V1.0_24Jan2025