Clinical trial of Oleogel topical treatment for EB

JS Kern[1]
1 Royal Melbourne Hospital, Parkville, VIC, Australia

Oleogel consists of two components only: refined sunflower oil and the active ingredient triterpens (TE) from birch bark dry extract. In preclinical studies TE have been shown to promote wound healing through different mechanisms, including transient inflammatory marker up-regulation, keratinocyte migration and differentiation. In phase 3 trials Oleogel has been shown to significantly accelerate wound healing in split thickness graft donor site and grade 2a burn wounds. Tolerability of Oeleogel is high. An observational case series and a phase 2 study in EB suggest efficiency and safety. The currently actively recruiting EASE trial is a global multicenter, phase 3, double blind, randomized, placebo (vehicle) controlled study. Patients with all EB subtypes can be enrolled. The 90-day double blind treatment period is followed by a 24-month open label single arm follow-up. The incidence of complete closure of the EB target wound is the primary endpoint, following guidance by the FDA.

References
1 Ebeling et al, Plos One 2014
2 Woelfle et al, J Invest Dermatol 2010
3 Barret et al, Burns 2017
4 Schwieger-Briel et al, Dermatol Res Pract 2017