

A Study to Learn About the Safety and Efficacy of the Drug Oleogel-S10 in Japanese Patients With Epidermolysis Bullosa

NCT06917690

Status	RECRUITING
Phase	Phase 3
Sponsor	Chiesi Farmaceutici S.p.A.
Enrollment	6 participants

Key Eligibility Criteria

Inclusion (23)

- Male or female aged e 21 days
- Confirmed diagnosis of either JEB or DEB
- Both biological parents and all 4 grandparents of Japanese descent
- At least 3 EB wounds that meet the following criteria at the time of enrollment:
- All are located outside of the anogenital region

... and 18 more (see full listing online)

Exclusion (13)

- Hypersensitivity to Oleogel-S10 or any of its excipients
- Diagnosis of EB subtypes simplex or Kindler EB
- Receipt of systemic antibiotics for wound-related infections within 7 days prior to enrollment
- Receipt of systemic or topical (on EB wounds) steroids within 30 days prior to enrollment Exceptions: Inhaled, ophthalmic, or mucosal applications, such as budesonide suspension for esophageal strictures
- Receipt of immunosuppressive therapy or cytotoxic chemotherapy within 60 days prior to enrollment Note: Dupilumab to manage pruritis is allowed if the subject has been on a stable dose for more than 3 months prior to baseline

... and 8 more (see full listing online)

Locations (6 total)

Fukuoka Children's Hospital - Dermatology, Fukuoka, Japan
Kurume University Hospital, Fukuoka, Japan
Kobe University Hospital, Kobe, Japan

... and 3 more locations