A Phase 2 Study of TCP-25 Gel in Patients With Epidermolysis Bullosa, STEP-study

NCT06594393

Status	RECRUITING
Phase	Phase 2
Sponsor	Xinnate AB
Enrollment	32 participants

Key Eligibility Criteria

Inclusion (2)

- Male or female patients with documented diagnosis of DEB or JEB, confirmed by genetic testing and/or by a skin biopsy with immunofluorescence mapping.
- Patients e4 years old. Note: Initially, patients e12 years will be enrolled. Enrollment will be open to 4 to 11 year old pediatric patients (both inclusive), after a DMC reviews and provides a positive opinion regarding the safety and tolerability of the IMP in at least 3 patients 12 to 18 years old who have completed at least 4 weeks of IMP use.

Exclusion (6)

- The patient has any subtype of EB other than DEB or JEB.
- The patient is currently being treated or planned to be treated with systemic antibiotics.
- Note: Use of preventive and/or anti-inflammatory antibiotic treatment, including doxycycline, on an established treatment regimen (stable dose for e6 weeks before the Baseline Visit) is permitted. Use of topical antibiotics on the index wounds within 7 days before the Baseline Visit is prohibited.
- • Use of systemic corticosteroids \>0.2 mg/kg prednisone dose equivalent per day within 30 days or use of topical corticosteroids on index wounds within 7 days before the Screening Visit.
- Note: Corticosteroids for inhalation, ophthalmic, or intranasal use are permitted.

... and 1 more (see full listing online)

Locations (6 total)

Hopital St Louis, Paris, France
Andreas Syngros Hospital of Veneral & Dermatological Diseases, Athens, Greece
Hospital Of Skin And Venereal Diseases of Thessaloniki, Thessaloniki, Greece
... and 3 more locations