Study to Evaluate Safety and Efficacy of ALLO-ASC-SHEET in Subjects With Dystrophic Epidermolysis Bullosa

NCT05157958

Status	RECRUITING
Phase	Phase 2
Sponsor	Anterogen Co., Ltd.
Enrollment	6 participants

Key Eligibility Criteria

Inclusion (8)

- Subject diagnosed as dystrophic epidermolysis bullosa confirmed by clinical criteria and one of the following:
- Immunostaining test: patients who have reduced or no type 7 collagen in staining degree of immunofluorescence. Other antigens (laminin-332, type 17 collagen, plectin, integrin ±6²4ype 5 and type 14 keratin, etc.) are normal in immune-staining.
- COL7A1 mutational analysis: confirmation of COL7A1 genetic mutation.
- Subject with skin ulcer lesions of dystrophic epidermolysis bullosa meet the following criteria, on the screening start day (Visit 1) and treatment start day (enrollment day) (Visit 3):
- Subject has two skin ulcer lesions judged as comparable to compare the safety and efficacy by investigator during screening period and prior to the IP application (enrollment day).

... and 3 more (see full listing online)

Exclusion (2)

- Subject who requires antibiotics due to bacterial infection on skin of the target skin ulcer area (area including ulcer lesion and surrounding area where the IP is to be applied).
- Female subjects: pregnant woman (indicated by serum hCG test result at screening), breast-feeding patient, all sexually active patient, with child bearing potential in case of female*, who is not willing to contracept** during the clinical trial.

Locations (1 total)

University of Miami Dermatology Clinical Trials Unit, Miami, Florida, United States