

MT2022-30: A double-blind, randomized, placebo-controlled, interventional, multicenter, phase III clinical trial to investigate the safety and efficacy of ABCB5-positive mesenchymal stromal cells (ABCB5+ MSCs) on epidermolysis bullosa (EB)", allo-APZ2-EB-III

Status: Recruiting

Eligibility Criteria

Sex: Male or Female

Age Group: Not specified

This study is NOT accepting healthy volunteers

Inclusion Criteria:

- confirmed diagnosis of RDEB or JEB - wound meeting the following criteria: 5-50 cm, present for at least 21 days and less than 9 months without signs of acute infection - women of childbearing potential, male participants, and their partner must be willing to use highly effective contraceptive methods during the course of the entire clinical trial

Exclusion Criteria:

- current cancer diagnosis including squamous cell carcinoma and basal cell carcinoma - women who are pregnant or breast feeding - clinically significant or unstable medical or mental health diagnosis (study staff will review)

Conditions & Interventions

Conditions:

Rare Diseases

Keywords:

EB, Epidermolysis Bullosa, RDEB

More Information

Description: This is a study of an investigational drug (also known as the "study drug") called allo-APZ2-OTS as a possible treatment for RDEB. The study drug contains allogeneic dermal ABCB5-positive mesenchymal stromal cells (ABCB5+ MSCs). These cells suppress inflammation and produce proteins that are important for wound healing. The study drug is expected to counteract local inflammation, improve wound healing and skin strength, and speed up wound closure.

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