MSC EVs in Dystrophic Epidermolysis Bullosa

NCT04173650

Status	RECRUITING
Phase	Phase 1, Phase 2
Sponsor	Aegle Therapeutics
Enrollment	8 participants

Key Eligibility Criteria

Inclusion (8)

- Subjects must be 6 months or older at screening.
- Subjects who have a confirmed diagnosis of DEB based on electron microscopy, immunomapping, or genetic testing. Subjects with severe DEB (e.g., RDEB patients with absent Col VII/no anchoring fibrils) and milder forms of DEB (e.g., RDEB patients with reduced Col VII and/or anchoring fibril levels) are eligible.
- Presence for at least four weeks of two 10 - 50 cm2 wounds (unroofed EB erosions) at least 4 inches apart that can be considered similar enough in size, wound location and expected healing characteristics to be a matched pair. Neither index wound may have been treated with any local (topical, subcutaneous, etc) or systemic therapeutic other than standard of care treatments described in this protocol (i.e. local or systemic antimicrobials to control infection, topical anesthetic and oral analgesics if required) in the past 3 months prior to screening.
- Females of childbearing potential must have a negative urine or serum pregnancy test at screening and agree to continue use of an acceptable form of birth control throughout the duration of the study. Acceptable forms of birth control include oral, implant, injectable, and transdermal contraceptives; an intrauterine device; or other forms considered acceptable by the investigator. A female subject is eligible to participate if she is not pregnant, is not a woman or childbearing potential (WOCBP), or is a WOCBP who agrees to follow the contraceptive guidance above.
- Post-pubertal males who agree to use an acceptable method of contraception for the duration of the study.

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

Exclusion (16)

- Concomitant treatment at the time of screening or at any time during the study of either study wound (control or AGLE-102 treated) with local or systemic therapy other than standard of care treatments described in this protocol (i.e. local or systemic antimicrobials to control infection, topical anesthetic and oral analgesics if required). Concomitant treatment of non-study wounds with local therapy during the study is acceptable. Systemic treatment of RDEB wounds (except as noted for standard of care) during the study is not acceptable. Subjects unwilling to abstain from prohibited concomitant treatment of study wounds (treated or control) and/or systemic treatment of RDEB wounds during the study period are excluded.
- Either study wound located within 6 inches of wounds treated concurrently with any other local therapy.
- Clinical evidence of systemic infection.
- History of bone marrow transplantation.
- Diagnosed clinically significant autoimmune disease

... and 11 more (see full listing online)

Locations (3 total)

Phoenix Children's Hospital, Phoenix, Arizona, United States
USC /Norris Comprehensive Cancer Center University of Southern California, Los Angeles, California, United States
Children's Hospital of Philadelphia, Philadelphia, Pennsylvania, United States