MT2015-36 : Study of Epidermal Grafting Using the CelluTome Epidermal Harvesting System for the Treatment of Individual Lesions in persons with Epidermolysis Bullosa

Status: Completed

Eligibility Criteria

Sex: All
Age: Not specified
This study is NOT accepting healthy volunteers

Inclusion Criteria:

Patient (Recipient)

• Diagnosis of Dystrophic Epidermolysis Bullosa (DEB) or Junctional Epidermolysis Bullosa (JEB) with at least one wound, visibly free from infection (or previously treated) and meets the eligibility for Arm A or Arm B based on the skin graft source:

• Cell harvest from previous hematopoietic cell transplantation (HCT) donor (Arm A) - not applicable if Arm B

• At least 6 months after hematopoietic cell transplantation with donor chimerism

• Peripheral blood donor chimerism should be measured within 21 days of grafting and be >/= 5% and stable. Stability of chimerism will be determined by the protocol team and based on 3 peripheral blood chimerism values at least 1 month apart.

• No history of pre-BMT autoimmune cytopenias

• Off immune suppressive therapy

• Original transplant donor is available and willing to be the epidermis donor

• Self-donation (Arm B)

•not applicable if Arm A

• Proven somatic reversion

• Site for skin grafting free of cellulitis and any other clinically evident abnormalities

• Meets donor eligibility

• Insurance pre-authorization for procedure, if applicable

• Voluntary written consent (patient or parent/guardian for minors with assent) prior to any research related procedures or treatment. Skin Graft Donor (either hematopoietic cell transplantation donor for the EB patient [Arm A] or EB patient herself/himself [Arm B])

• Age > 2 years (based on prior safety testing of the device)

• Healthy on physical examination in the opinion of the evaluating provider

• Negativity for Hepatitis B and C, HIV, and HTLV1/2 within 30 days of donation

• Voluntary written consent (donor or parent/guardian for minors with assent) prior to any research related procedures

Conditions & Interventions

Interventions:
Device: Cellutome Epidermal Harvesting System
Conditions:
Epidermolysis Bullosa

More Information

Description: The primary study objective is to achieve > 50% wound closure within 12 weeks of skin grafting. Secondary objectives are to [1] assess safety, longevity and functionality of grafted skin in the recipient over the period of 1 year, [2] measure changes in quality of life through pain, itching and general QOL questionnaires and [3] safety and seamless, scar-free healing of the body sites of the donor from which epidermis has been harvested over the period of 1 year.
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