BURNS

BA Study

STUDY DESCRIPTION

Phase IIb, prospective, intra-patient randomized controlled, multicenter study to evaluate the safety and efficacy of x for the treatment of partial deep dermal and full thickness burns in adults and adolescents in comparison to autologous split-thickness skin grafts.

STUDY OBJECTIVE

To evaluate the efficacy and safety of x in comparison to meshed STSG in adults and adolescents with deep partial and full-thickness burns.

PATIENT POPOLATION

12 evaluable patients that could be inflated up to 15 patients.

TREATMENT PERIOD

Clinical Evaluation phase: Pretreatment phase – Treatment phase (transplant, day 0) – Post Treatment Phase (up to 1 year from grafting)

PRIMARY EFFICACY PARAMETERS

Ratio of covered surface area to biopsy site/donor site surface area at 28 days post grafting. Secondary: percentage of epithelialization at 90 days post grafting

STUDY DETAILS

Total number of patients: 15
Recruitment period: 5 years and 5 months
First patient in: March 23, 2018
Last patient out (clinical evaluation phase): August 31, 2023
Exploratory phase: ongoing

SINTESI RESEARCH SERVICES

Project management, regulatory, interaction with sites, monitoring and archiving for Italy.

KEY CHALLENGES

► Study sites with very limited personnel
► Study sites with limited experience in clinical trial conduction
► Acute pathology on study, that required very fast evaluation and interaction with sites to manage pre-treatment study procedures.
► Study with ATMP (additional regulatory documentation needed throughout the study and longer evaluation timelines)
► Study with vulnerable population (pediatric patients, unconscious patients)
► GCP audit from Sponsor (external auditor)

To discover Sintesi Research services contact us:

Sintesi Research – Via Delle Stelline 9, 20146 Milano – Italy
Phone: 02.87.35.12 Mail: info@sintesiresearch.com
www.sintesiresearch.com