BURNS

BC 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 children in comparison to autologous split-thickness skin grafts.

STUDY OBJECTIVE
To evaluate the efficacy and safety of x in comparison to meshed STSG in pediatric patients with deep partial and full-thickness burns.

PATIENT POPOLATION
12 evaluable patients

TREATMENT PERIOD
Clinical Evaluation phase: Pre treatment phase – Treatment phase (transplant, day 0) – Post Treatment Phase (up to 1 year from grafting)
Exploratory phase: Long-term Follow-up (up to 3 years 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: 5/12
Recruitment period: ongoing
First patient in: November 14, 2017
Last patient out (clinical evaluation phase): NA, ongoing
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)
► 6 substantial amendments submitted in 4 years
► GCP audit from Sponsor (external auditor)

To discover Sintesi Research services contact us:

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