BURNS

RAC Study

STUDY DESCRIPTION

Phase II, prospective, intra-patient randomized controlled, multicenter study to evaluate the safety and efficacy of x for the treatment of full-thickness skin defects in adults and children in comparison to autologous split-thickness skin grafts.

STUDY OBJECTIVE

To evaluate the efficacy and safety of x in comparison to STSG in adults and children with non-acute large full-thickness skin defects.

PATIENT POPOLATION

20 evaluable patients that could be inflated to 25 patients.

TREATMENT PERIOD

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

Scar quality at the study areas in comparison to control areas at 90 days post grafting.

STUDY DETAILS

Total number of patients: 21
Recruitment period: 5 years and 8 months
First patient in: March 7, 2018
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
► Study with ATMP (additional regulatory documentation needed throughout the study and longer evaluation timelines)
► Study with vulnerable population (pediatric patients)
► 5 substantial amendments submitted in 4 years
► GCP audit from Sponsor (external auditor)

To discover Sintesi Research services contact us:

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