

The effect of CUTICERIN® with or without a Regenerative Epithelial Suspension (RES™), on pigmentation of donor sites in children: The pilot randomised DRESSIng Trial

ACTRN12620000227998

Status	RECRUITING
Sponsor	Department of Industry , Innovation and Science
Enrollment	40 participants

Plain Language Summary

When children suffer serious burns and need skin graft surgery, the area where the skin is taken from (the donor site) can heal with abnormal colour — appearing lighter or darker than the surrounding skin. This colour difference can cause significant distress to children and their families, and is difficult for clinicians to treat.

This study tests whether applying a mixture of the child's own skin cells (called Regenerative Epithelial Suspension, or RES) to the donor site, alongside standard wound dressings, improves the colour of the healed skin at 12 months after surgery. The RES is prepared using a device called RECELL, which processes a small sample of skin to create a liquid containing skin-regenerating cells that are then sprayed onto the wound.

Eligibility is for children under 16 years of age who have an acute burn requiring a split-thickness skin graft, where the donor site is not larger than 320 square centimetres and the recipient site not larger than 400 square centimetres. The child and guardian must be willing and able to attend all follow-up visits. Children with a known allergy to trypsin or sodium lactate, or with a previous adverse reaction to general anaesthesia, are not eligible.

Key Eligibility Criteria

Inclusion (4)

- Acute burn injury requiring a split thickness skin graft for which:
 - a. The donor site for evaluation should not exceed 320 sqcm.
 - b. The split-thickness skin graft recipient site for evaluation should not exceed 400 sqcm.
- Child (and/or accompanying guardian) is willing and able to complete all follow-up evaluations required by the study protocol.

Exclusion (5)

- Non-English-Speaking Background
- Child in the care of the Department of Community Services
- Full thickness skin graft
- Hypersensitivity to trypsin or sodium lactate.
- Previous adverse reaction to general anaesthesia.

Locations (1 total)

Queensland Children's Hospital - South Brisbane, QLD, Australia

<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12620000227998>

DISCLAIMER: This document is for informational purposes only and does not constitute medical advice. Always consult your healthcare provider before enrolling in any clinical trial. Information may not be up to date — verify details at anzctr.org.au. Generated by ClinicalTrialsFinder.org.