Which skin adhesive works best for kids' surgery wounds?

Submission date	Recruitment status Not yet recruiting	[X] Prospectively registered		
16/12/2025		[X] Protocol		
Registration date 29/12/2025 Last Edited 29/12/2025	Overall study status Ongoing Condition category Injury, Occupational Diseases, Poisoning	Statistical analysis plan		
		Results		
		☐ Individual participant data		
		[X] Record updated in last year		

Plain English summary of protocol

Background and study aims

This study is looking at three different ways to cover surgical wounds in children after an operation: a clear film dressing, a padded dressing, and skin glue. Doctors use all of these methods, but we don't know which is best for children. The aim is to find out which option is safest, most comfortable, and most cost-effective.

Who can participate?

Children aged 3 to 14 years who are having surgery with stitches can take part, as long as their parents give consent. Children with allergies to adhesives or very dirty wounds will not be included.

What does the study involve?

Children who join the study will be randomly given one of the three wound coverings after their operation. Doctors and nurses will apply it using a standard procedure. Follow-up checks will happen in hospital and then at 7 days and 60 days after surgery.

What are the possible benefits and risks of participating?

Taking part could help improve care for children after surgery and reduce stress for families. There are no extra risks beyond normal surgery, but some wound coverings may be more or less comfortable or need more changes.

Where is the study run from? University of Jordan

When is the study starting and how long is it expected to run for? January 2026 to April 2027

Who is funding the study? Deanship of Scientific Research, University of Jordan

Who is the main contact? r.altaher@ju.edu.jo

Contact information

Type(s)

Public, Scientific, Principal investigator

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Additional identifiers

Study information

Scientific Title

Transparent vs padded vs topical skin adhesive for pediatric surgical wounds - a multicenter, randomized controlled study

Study objectives

Primary Objective:

To determine whether TSA reduces 60-day incisional wound morbidity compared with NTPD, and TNPD in pediatric surgical patients with primarily closed wounds.

Secondary Objectives:

- 1. Compare pain trajectories, patient/parent anxiety, comfort, and caregiver satisfaction across arms.
- 2. Compare surgical site infection (SSI) rates, dehiscence, seroma/hematoma requiring intervention.
- 3. Evaluate resource use (dressing changes, clinic/ED visits) and direct material costs.
- 4. Explore cosmetic outcomes at 60 days using a validated scar scale.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 06/11/2025, Institutional Review Board at Jordan University Hospital (Queen Rania Street, Amman, 13046, Jordan; +962 (0)65353444; juhosp@ju.edu.jo), ref: 10/2025/29349

Primary study design

Interventional

Allocation

Randomized controlled trial

Masking

Blinded (masking used)

Control

Active

Assignment

Parallel

Purpose

Device feasibility, Health services research, Supportive care

Study type(s)

Health condition(s) or problem(s) studied

Skin adhesive for pediatric surgical wounds

Interventions

The randomization process is centralized and web-based, utilizing permuted blocks stratified by site (center) and generated using Microsoft Copilot. Allocation is sequential upon the already prepared list for each center.

Arm A — Transparent Non-Padded Dressing (TNPD): sterile transparent film sized to cover incision plus 2–3 cm margin. Dressing removal per protocol on POD 3–5 unless soiled/detached. Arm B — Non-Transparent Padded Dressing (NTPD): sterile non-transparent pad with adhesive borders. Dressing removal per protocol on POD 3–5 unless soiled/detached. Arm C — Topical Skin Adhesive (TSA) cyanoacrylate-based (Glubran® Tiss 2 0.25ml): applied in two thin layers along approximated incision; allowed to polymerize fully; no additional dressing unless clinically indicated.

Intervention Type

Procedure/Surgery

Primary outcome(s)

1. Incisional wound morbidity measured using Observation at 24-48 hours, 7 days +/-2, 60 days +/- 10

Key secondary outcome(s))

- 1. Pain scores measured using Wong–Baker FACES scale at 24-48 hours, 7 days +/-2, 60 days +/-10
- 2. Parental satisfaction measured using Questionnaire at 24-48 hours, 7 days +/-2, 60 days +/- 10
- 3. Dressing-related complications measured using Observation at 24-48 hours, 7 days +/-2, 60 days +/-10

4. Cost measured using Direct calculations at after final enrolment

Completion date

15/04/2027

Eligibility

Key inclusion criteria

- 1. Age 3–14 years.
- 2. Undergoing clean/clean-contaminated surgery with primary skin closure with absorbable/non-absorbable sutures, either interrupted or subcuticular.
- 3. Surgical category (head and neck, chest, abdomen, back, genitalia, and extremities).
- 4. Anticipated need for immediate post-operative wound coverage (dressing or TSA).
- 5. Informed consent from parent/guardian.

Healthy volunteers allowed

No

Age group

Child

Lower age limit

3 years

Upper age limit

14 years

Sex

All

Total final enrolment

0

Key exclusion criteria

- 1. Known allergy/sensitivity to cyanoacrylates, adhesive tapes, or dressing components.
- 2. Presence of surgical drains exiting through the primary incision.
- 3. Contaminated/dirty wounds.
- 4. Immunocompromised states where protocol interventions are contraindicated.

Date of first enrolment

18/01/2026

Date of final enrolment

17/01/2027

Locations

Countries of recruitment

Jordan

Study participating centre Jordan University Hospital Jordan

Study participating centre Queen Rania Children's Hospital Jordan

Study participating centre Al-Basheer HospitalJordan

Study participating centre King Abdullah II University Hospital Jordan

Sponsor information

Organisation

University of Jordan

ROR

https://ror.org/05k89ew48

Funder(s)

Funder type

Funder Name

Deanship of Scientific Research, University of Jordan

Alternative Name(s)

The Deanship, Deanship of Scientific Research, Deanship of Scientific Research at the University of Jordan, , DSR

Funding Body Type

Government organisation

Funding Body Subtype

Research institutes and centers

Location

Jordan

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files	Data collection sheet		29/12/2025	No	No
<u>Protocol file</u>			29/12/2025	No	No