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Which skin adhesive works best for kids' surgery wounds?

Submission date
16/12/2025

Recruitment status
Recruiting

Registration date
29/12/2025

Overall study status
Ongoing

Last Edited
29/12/2025

Condition category
Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[X] Protocol
[_] 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?
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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 Hospital
Jordan

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
Protocol file			29/12/2025	No	No