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This study investigated whether acupressure could reduce pain, fear, and anxiety during port insertion in pediatric cancer patients.

Submission date
04/10/2025

Recruitment status
No longer recruiting

Registration date
10/10/2025

Overall study status
Completed

Last Edited
15/10/2025

Condition category
Signs and Symptoms

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Children with cancer often require Port-A catheters for the safe administration of chemotherapy, blood transfusions, blood draws, antibiotics, and other treatments. A Port-A is a venous access device implanted beneath the chest skin. It requires needle puncture using a Huber needle, which causes pain and is a common source of anxiety and fear among hospitalized children with cancer. Some children experience extreme anxiety, resist needle insertion, or develop psychological trauma, which can affect treatment compliance and timeliness. The pain associated with Port-A needle insertion also causes stress for parents. Reducing the distress caused by needle procedures in children with cancer is a key goal for healthcare providers. Traditional Chinese medical acupressure has been shown in multiple empirical studies to have analgesic and Anxiety effects. This study aims to evaluate the safety and effectiveness of acupressure in relieving pain and reducing anxiety during Port-A needle insertion in children with cancer.

Who can participate?
Children with cancer aged 4–12 years who are undergoing Port-A catheter needle insertion.

What does the study involve?
Participants are randomly assigned to either an experimental group (acupressure) or a control group (nursing routine care). The experimental group receives acupressure at the Neiguan (PC6) and Hegu (LI4) points during needle insertion, while the control group receives standard nursing care. Measurements before and after needle insertion include physiological parameters (respiratory rate, heart rate, blood pressure, mean arterial pressure), the Faces Pain Scale–Revised (FPS-R), the Children's Fear Scale (CFS), pretest scores on the Children's Anxiety Meter–State (CAMS), and the Children's Emotional Manifestation Scale (CEMS) during needle insertion.

What are the possible benefits and risks of participating?
Benefits: Participants may experience reduced pain and fear during needle insertion.
Risks: The skin at the acupressure site will be monitored for redness, swelling, heat, or pain during the intervention.

Where is the study run from?
Chang Gung Memorial Hospital, Taoyuan, Taiwan — Pediatric Oncology Ward and Pediatric Oncology Outpatient Treatment Room

When is the study starting and how long is it expected to run for?
February 2024 to May 2025

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Study information

Scientific Title
The effects of acupressure intervention on pain, fear, and anxiety in pediatric cancer patients during port catheter needle insertion: a randomized controlled trial

Acronym
APPC

Study objectives
To evaluate the safety and effectiveness of Traditional Chinese Medicine (TCM) acupressure in relieving pain and reducing anxiety in children with cancer undergoing port catheter needle insertion.

Ethics approval required

Ethics approval required

Ethics approval(s)
approved 21/05/2024, Chang Gung Medical Foundation Institutional Review Board (199, Tung Hwa North Road, Taipei, 10507, Taiwan; +886 (03) 3196200; irb1@cgmh.org.tw), ref: 202400725B0

Study design
Single center interventional single-blinded randomized controlled trial

Primary study design
Interventional

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Reducing pain associated with port insertion in children with cancer

Interventions
The study uses a randomized controlled design. This study adopts a block randomization method using the online tool available at (https://www.sealedenvelope.com/simple-randomiser/v1/lists).

Randomization divides children into two groups: an experimental group (acupressure group) and a control group (nursing routine care).

Experimental Group (Acupressure Group):
Children receive Neiguan (PC6) acupressure for five minutes before needle insertion. During the needle insertion, Hegu (LI4) acupressure is performed for five minutes. Acupressure is applied with the thumb pad pressing vertically with moderate and steady force, gradually increasing from light to moderate intensity. Pressure is held for 5 seconds and released for 1 second, repeated for 5 minutes per point, with two points pressed for about 10 minutes in total.

Control Group: (nursing routine care)
Children receive routine nursing care without acupressure.

Each pediatric patient underwent one assessment before and one assessment after the Port-a-Cath access injection.

Intervention Type
Procedure/Surgery

Primary outcome(s)
The effect of acupressure on pain and fear during Port-A needle insertion in pediatric cancer patients measured using the Faces Pain Scale – Revised (FPS-R) and Children’s Fear Scale (CFS) before and after the Port-A access injection

Key secondary outcome(s))
The following secondary outcome measures were assessed before and after the Port-A access injection:
1. Physiological indicators (respiration, heart rate, blood pressure, mean arterial pressure)

measured using standard procedures
2. Parental observation of the child's pain and fear measured using the Faces Pain Scale – Revised (FPS-R) and Children's Fear Scale (CFS)
3. Blinded nurse assessment of the child's behavioral responses measured using the Children's Emotional Manifestation Scale (CEMS)
4. Assessment of the correlation among pain, fear, and anxiety measured using the Children's Anxiety Meter–State (CAMS), Faces Pain Scale–Revised (FPS-R), and Children's Fear Scale (CFS)

Completion date
31/05/2025

Eligibility

Key inclusion criteria
1. Pediatric cancer diagnosis (Western medicine criteria)
2. Undergoing port catheter needle insertion
3. Age 4–12 years
4. Stable vital signs
5. Platelet count >20,000/μl, no acute bleeding tendency
6. Child willing to receive acupressure
7. Parents provide informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
4 years

Upper age limit
12 years

Sex
All

Total final enrolment
62

Key exclusion criteria
1. Unstable vital signs (fever, shortness of breath, tachycardia, low blood pressure)
2. Skin infection, injury, or ulcer at the massage site
3. Severe comorbidity (cardiovascular, infectious diseases)
4. Unable to cooperate with acupressure

Date of first enrolment

03/06/2024

Date of final enrolment
23/05/2025

Locations

Countries of recruitment
Taiwan

Study participating centre
Graduate Institute of Clinical Medical Sciences Chang Gung University
No. 259, Wenhua 1st Rd., Guishan Dist.
Taoyuan City
Taiwan
33302

Sponsor information

Organisation
Chang Gung University

ROR
https://ror.org/00d80zx46

Funder(s)

Funder type
Other

Funder Name
Investigator inittiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from En-Chen Fang, fang7739ccf@gmail.com, D100503@cgu.edu.tw.
i. The type of data that will be shared.
All of the individual participant data collected during the trial, after deidentification.

ii. Timing for availability
Immediately following publication. No end date.
iii. Whether consent from participants was required and obtained
Informed consent was obtained from all participants.
iv. Comments on data anonymization
All participant data were fully anonymized before analysis and data sharing. No personal identifiers were included in the shared dataset.
v. Any ethical or legal restrictions
There are no known ethical or legal restrictions on sharing the anonymized data.
vi. Any additional comments
There are no additional comments.

IPD sharing plan summary

Available on request