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

| Submission date | Recruitment status | Prospectively registered |
|-------------------|----------------------|--|
| 04/10/2025 | No longer recruiting | ☐ Protocol |
| Registration date | Overall study status | Statistical analysis plan |
| 10/10/2025 | Completed | Results |
| Last Edited | Condition category | Individual participant data |
| 15/10/2025 | Signs and Symptoms | [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?

- 1. En-Chen Fang, Postgraduate Student, Graduate Institute of Clinical Medical Sciences, Chang Gung University, fang7739ccf@gmail.com, D1000503@cgu.edu.tw
- 2. Jiun-Liang Chen, Assistant Professor, Graduate Institute of Clinical Medical Sciences, Chang Gung University, a12015@adm.cgmh.org.tw

Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

Ms En-Chen Fang

Contact details

No. 8, Ln. 35, Sec. 2, Yong'an N. Rd., Sanchong Dist. New Taipei City Taiwan 241756 +886 905367739 D1000503@cgu.edu.tw

Additional identifiers

Clinical Trials Information System (CTIS)

Nil Known

ClinicalTrials.gov (NCT)

Nil Known

Protocol serial number

Nil Known

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

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

Study outputs

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet Participant information sheet 11/11/2025 11/11/2025 No Yes