**ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt**
Release Date: December 16, 2023

**ClinicalTrials.gov ID: NCT05851625**

## Study Identification

| | |
|---|---|
| Unique Protocol ID: | 19944 |
| Brief Title: | Efficacy of Ear Acupuncture in Preventing Chemotherapy Induced Nausea and Vomiting in Cancer Patients |
| Official Title: | Efficacy of Ear Acupuncture in Preventing Chemotherapy Induced Nausea and Vomiting in Cancer Patients |
| Secondary IDs: | |

## Study Status

| | |
|---|---|
| Record Verification: | December 2023 |
| Overall Status: | Recruiting |
| Study Start: | October 16, 2023 [Actual] |
| Primary Completion: | January 31, 2024 [Anticipated] |
| Study Completion: | February 28, 2024 [Anticipated] |

## Sponsor/Collaborators

| | |
|---|---|
| Sponsor: | Indonesia University |
| Responsible Party: | Principal Investigator<br>Investigator: Wahyuningsih Djaali [wdjaali]<br>Official Title: Lecturer of Indonesia University<br>Affiliation: Indonesia University |
| Collaborators: | Mashhad University of Medical Sciences |

## Oversight

| | |
|---|---|
| U.S. FDA-regulated Drug: | No |
| U.S. FDA-regulated Device: | No |
| U.S. FDA IND/IDE: | No |
| Human Subjects Review: | Board Status: Approved<br>Approval Number: KET-785/UN2F1/ETIK/PPM0002/2023<br>Board Name: Komite Etik Penelitian Kesehatan FKUI/RSCM<br>Board Affiliation: Faculty of Medicine Universitas Indonesia<br>Phone: +6221 315 7008<br>Email: ec_fkui@yahoo.com<br>Address: |

Jl. Salemba 6, Jakarta Pusat, DKI Jakarta, Indonesia

Data Monitoring: Yes

FDA Regulated Intervention: No

## Study Description

Brief Summary: Chemotherapy is a cancer therapy performed on advanced cancer with quite good success, but this therapy has quite a lot of side effects. Chemotherapy induced nausea and vomiting or commonly known as CINV, is a condition of nausea and vomiting experienced by cancer patients undergoing chemotherapy, with a prevalence of around 80% of all patients undergoing chemotherapy, and 40% has the potential to become severe. This study aims to determine the efficacy of a new acupuncture modality, namely the press needle, in preventing CINV symptoms in pediatric patients with cancer undergoing chemotherapy.

The study was conducted using a randomized controlled clinical trial (RCT) design in 64 pediatric cancer patients undergoing chemotherapy who were randomized into 2 groups, namely: (1) standard medical therapy as the control group; and (2) a combination of standard therapy with press needle acupuncture as the treatment group. The ear acupuncture points used are Shenmen and Stomach, and one body acupuncture point is PC6. Outcome measurements were carried out in the form of the RINVR questionnaire to assess the intensity of nausea and vomiting measured at 4 times: (1) 3 days before chemotherapy; (2) days of chemotherapy; (3) 12 hours after chemotherapy; (4) 3 days after chemotherapy.

Detailed Description:

## Conditions

Conditions: Pediatric Cancer
Chemotherapy-induced Nausea and Vomiting
Chemotherapy Effect

Keywords: acupuncture
ear acupuncture
CINV
cancer
press needle

## Study Design

Study Type: Interventional

Primary Purpose: Prevention

Study Phase: N/A

Interventional Study Model: Parallel Assignment

Number of Arms: 2

Masking: Single (Participant)

Allocation: Randomized

Enrollment: 64 [Anticipated]

## Arms and Interventions

| Arms | Assigned Interventions |
|---|---|
| Placebo Comparator: Placebo<br>The control group was given a placebo press needle acupuncture (using plaster) with standard medical therapy for CINV prevention. | Device: Plesterin<br>The plaster used is a round plaster that resembles the shape of an acupuncture press needle. |
| Experimental: Acupuncture<br>The intervention group was given press needle acupuncture with standard medical therapy for CINV prevention. | Device: Press needle acupuncture<br>Press needle acupuncture is a modality of acupuncture using tiny and very thin needles. |

## Outcome Measures

Primary Outcome Measure:

1. Rhodes Index of Nausea, Vomiting, and Retching (RINVR) questionnaire
   Method instrument for assessing nausea and vomiting consisting of eight statements

   [Time Frame: 9 days]

## Eligibility

Minimum Age: 6 Years

Maximum Age: 18 Years

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Pediatric patients with cancer who are undergoing chemotherapy.
- Age 6 – 18 years.
- Patients with platelet counts > 20,000/μL and neutrophil values > 1,000/μL.
- Willing to follow the research.

Exclusion Criteria:

- Patients with local infection in the puncture area.
- Patients with anatomic abnormalities in the auricle.
- Did not complete the acupuncture therapy until it was finished (three days after chemotherapy).

## Contacts/Locations

Central Contact Person: Wahyuningsih Djaali
Telephone: +6281381117386
Email: inchy86@yahoo.com

Central Contact Backup:

Study Officials:

Locations: **Indonesia**
RSUPN Dr. Cipto Mangunkusumo
[Recruiting]
Jakarta, DKI Jakarta, Indonesia, 10430

Contact: Wahyuningsih Djaali

## IPDSharing

Plan to Share IPD: Undecided

## References

Citations:

Links:

Available IPD/Information: