

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jun 2026

The Effect Of Acupressure On Nausea And Vomiting And Anxiety Induced By Chemotherapy In Schoolchildren With Acute Lymphoblastic Leukemia

Protocol summary

Study aim

The general goal of determining the effect of acupressure on nausea and vomiting and anxiety caused by chemotherapy in school-age children with Acute lymphoblastic leukemia

Design

A clinical trial with a control group, one blind, randomized, sample size of 60 children with Acute lymphoblastic leukemia

Settings and conduct

The place of the study in the Amir Kabir Hospital of Arak. 60 Children with acute lymphocytic leukemia are randomly divided into two groups of intervention and control. Acupressure intervention at pericardium (p6) to reduce nausea and vomiting. The first day of chemotherapy 1 hour after the end of the first chemotherapy (3 times each time for 1 minute). Thirty minutes to one hour after the end of each pericardium interference, a subsequent intervention of acupressure at the Shen men point to reduce anxiety (3 times per minute for 1 minute). In the control group, on the first day of chemotherapy and one hour after the end of the first-order chemotherapy, acupressure intervention was performed at the false point of S13. (3 times each time for 1 minute).

Participants/Inclusion and exclusion criteria

Sample specification and entry criteria: Knowledge of time and place; Knowledge and history of using acupressure for any purpose; There is no specific problem in the place and place of acupressure (no scar, ecchymosis, mass or pain); Not suffering from certain chronic diseases (hemophilia, diabetes ...); Literacy, reading and writing, and the ability to complete a questionnaire (by the child or with the help of parents); do not have platelet less than 50,000 (due to the possibility of pressure-related bleeding); In the past six months, there has been no anxious event, such as the death of a first-degree relative, divorce, or father-in-work unemployment; Parents are not from the medical group.

Exit criteria: Possible death; Possible exemption from continuing participation in a potential; transfer study to a health facility in another city.

Intervention groups

Acupressure intervention at pericardium (p6) to reduce nausea and vomiting. The first day of chemotherapy 1 hour after the end of the first chemotherapy (3 times each time for 1 minute). Thirty minutes to one hour after the end of each pericardium interference, a subsequent intervention of acupressure at the Shen men point to reduce anxiety (3 times per minute for 1 minute). In the control group, on the first day of chemotherapy and one hour after the end of the first-order chemotherapy, acupressure intervention was performed at the false point of S13. (3 times each time for 1 minute).

Main outcome variables

Expected Outcome REDUCE Nausea and Vomiting and Anxiety Induce by Chemotherapy in Children with Acute Lymphoblastic Leukemia

General information

Reason for update

Acronym

-

IRCT registration information

IRCT registration number: **IRCT20170925036408N2**

Registration date: **2018-03-17, 1396/12/26**

Registration timing: **registered_while_recruiting**

Last update: **2018-03-17, 1396/12/26**

Update count: **0**

Registration date

2018-03-17, 1396/12/26

Registrant information

Name

mahbobe moogooei

Name of organization / entity

islamic azad university of medical sciences of Tehran

Country

Iran (Islamic Republic of)

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mina5041@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

-

Expected recruitment start date

2017-12-22, 1396/10/01

Expected recruitment end date

2018-12-22, 1397/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect Of Acupressure On Nausea And Vomiting And Anxiety Induced By Chemotherapy In Schoolchildren With Acute Lymphoblastic Leukemia

Public title

The Effect Of Acupressure On Nausea And Vomiting And Anxiety Induced By Chemotherapy In Schoolchildren With Acute Lymphoblastic Leukemia

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Knowledge of time and place; Knowledge and history of using acupressure for any purpose; There is no specific problem in the place and place of acupressure (no scar, ecchymosis, mass or pain); Not suffering from certain chronic diseases (hemophilia, diabetes ...); Literacy, reading and writing, and the ability to complete a questionnaire (by the child or with the help of parents); do not have platelet less than 50,000 (due to the possibility of pressure-related bleeding); In the past six months, there has been no anxious event, such as the death of a first-degree relative, divorce, or father-in-work unemployment; Parents are not from the medical group.

Exclusion criteria:

Exit criteria: Possible death; Possible exemption from continuing participation in a potential; transfer study to a health facility in another city.

Age

From **6 years** old to **12 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The placement of the samples will be randomized and blocked in both interventional and control groups. They will be considered for the age of 1 year and gender (male and female). The first eligible patient will be randomly selected. Will be in the group or intervention (so that the envelope containing the intervention or control group is selected by one of the personnel of the department). The next patient will be in the opposite position if it matches the age and sex. Otherwise The new lottery will be done to get 30 samples in the intervention group and 30 in the control group

Blinding (investigator's opinion)

Single blinded

Blinding description

use of the false point in the control group

Placebo

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee on Research in Islamic Azad University, Tehran Medical Branch

Street address

Islamic Azad University, Tehran Medical Sciences Branch, Khaghani St, Shariati St, Tehran.

City

tehran

Province

Tehran

Postal code

1916893813

Approval date

2017-11-07, 1396/08/16

Ethics committee reference number

ir.iau.tmu.rec.1396.185

Health conditions studied**1****Description of health condition studied**

Acute lymphoblastic leukemia

ICD-10 code

C91.0

ICD-10 code description

Acute lymphoblastic leukemia [ALL]

Primary outcomes

1

Description

Reduce nausea and vomiting

Timepoint

Before the intervention, immediately and 12 hours after the third intervention

Method of measurement

Visual Scale-Adjusted Rhodes Questionnaire for Children

2

Description

Reduce anxiety

Timepoint

Before the intervention, immediately and 12 hours after the third intervention

Method of measurement

Visual Scale

Secondary outcomes

1

Description

-

Timepoint

-

Method of measurement

-

Intervention groups

1

Description

Intervention group: Acupressure on the first day of chemotherapy and 1 hour after the end of chemotherapy at the pericardium 6 point to reduce nausea and vomiting (3 times and 1 minute for each) and 1 hour after acupressure in Pericardium point Acupressure intervention on the Shen Men point (3 times and 1 minute for each) to reduce anxiety.

Category

N/A

2

Description

Control group: On the first day of chemotherapy and 1 hour after the end of acupressure chemotherapy at the false S13 point for reduction of nausea and vomiting and anxiety (3 times and 1 minute for each)

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir Kabir Medical Education Center

Full name of responsible person

dr.Eghbali Aziz

Street address

Shahid Shiroodi Street, Alam al-Hoda Street, Nursing field of Amir Kabir Medical Education Center., Arak

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Fatemeh Alaei Kerahroodi

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Islamic Azad University

Proportion provided by this source

1

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Islamic Azad University
Full name of responsible person
Moogooei Mahbobe
Position
Senior Nursing Student
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Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available