Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 lumphocytic 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

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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 grou
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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+98 86 3313 5210
Email
aziz-eghbali@yahoo.com
Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Fatemeh Alaee Kerahroodi
Street address
Islamic Azad University, Tehran Medical Sciences Branch, Khaghani St., Shariati St., Tehran.
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falaee@iautmu.ac.ir
Web page address
HTTP://WWW.IAUMU.AC.IR
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

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Contact

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Mahbobe moogooei

Position

Nursing Graduate student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Web page address

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