Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effect of acupressure on the amount and intensity of nausea, vomiting and the level of comfort of children with leukemia undergoing chemotherapy

Protocol summary

Study aim
Determining the effect of acupressure on the amount and severity of nausea, vomiting and the level of comfort of children with leukemia undergoing chemotherapy

Design
Intervention

Settings and conduct
Ekbatan Hospital affiliated to Hamadan University of Medical Sciences

Participants/Inclusion and exclusion criteria
Children 6-12 years old with leukaemia Under chemotherapy Treated with a fixed dose of chemotherapy Not having digestive diseases

Intervention groups
Intervention group: Acupressure wristband group: First, the P6 point on the left hand is closed on the inner side of the forearm, in the cavity between the bones of the forearm, with a distance of three fingers above the fold of the wrist, then the wristband is fixed on the P6 point with a push button for 30 minutes. to be able to press the mentioned point. This intervention is performed 30 minutes before chemotherapy and then 30 minutes before breakfast, lunch and dinner on the first, second and third day after chemotherapy and each time for 30 minutes.

Main outcome variables
Nausea and vomiting and patient comfort

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190703044082N10**
Registration date: **2024-07-04, 1403/04/14**
Registration timing: **registered_while_recruiting**
Last update: **2024-07-04, 1403/04/14**
Update count: **0**

Registration date
2024-07-04, 1403/04/14

Registrant information

Name
Fateme Mohammadi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 81 4567 8904

Email address
f-mohammadi@umsha.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-05-20, 1403/02/31

Expected recruitment end date
2024-07-21, 1403/04/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of acupressure on the amount and intensity of nausea, vomiting and the level of comfort of children with leukemia undergoing chemotherapy

Public title
Investigating the effect of acupressure on the amount and intensity of nausea, vomiting and the level of

comfort of children with leukemia undergoing chemotherapy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Children 6-12 years old with leukaemia Under chemotherapy Treated with a fixed dose of chemotherapy Not having digestive diseases

Exclusion criteria:

Age

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

Gender

Both

Phase

1

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **111**

Randomization (investigator's opinion)

Randomized

Randomization description

To randomly assign the participants to the acupressure, placebo and control groups, the names of the three groups will be written on paper and taken randomly, and the order of sampling of the groups will be determined. 20 blocks of 6 will be used for random allocation of samples in three groups. In this way, the letter A will be considered for the acupressure group, the letter B for the placebo group, and the letter C for the control group. on pieces of paper, and we will pick them randomly. Then, according to the possible order of sampling, it will start.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients are blinded to the allocation of which group they will be placed in. That is, children and their families are unaware of whether they have been placed in the acupressure, placebo and control groups. In addition, the person who collected the data is blinded to the assignment of individuals to groups

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research ethics committee of Hamadan University of Medical Sciences

Street address

Beginning of Ayatollah Kashani Boulevard, Hamadan University of Medical Sciences and Health Services

City

Hamadan

Province

Hamadan

Postal code

6817838698

Approval date

2024-07-01, 1403/04/11

Ethics committee reference number

IR.UMSHA.REC.1403.198

Health conditions studied

1

Description of health condition studied

leukemia

ICD-10 code

C91

ICD-10 code description

Lymphoid leukemia

Primary outcomes

1

Description

frequency and severity of nausea and vomiting

Timepoint

Before chemotherapy and at the end of the first, second and third day after chemotherapy

Method of measurement

Rhodes Nausea and Vomiting Index adapted for children by parents

2

Description

Patient comfort

Timepoint

Before chemotherapy and at the end of the first, second and third day after chemotherapy

Method of measurement

visual analog scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Acupressure wristband group: First, the P6 point on the left hand is closed on the inner side of the forearm, in the cavity between the bones of the forearm, with a distance of three fingers above the fold

of the wrist, then the wristband is fixed on the P6 point with a push button for 30 minutes. to be able to press the mentioned point. This intervention is performed 30 minutes before chemotherapy and then 30 minutes before breakfast, lunch and dinner on the first, second and third day after chemotherapy and each time for 30 minutes.

Category

Treatment - Other

2

Description

Placebo group: wristband without push button is used. For this purpose, point P6 is determined and the wristband is closed 30 minutes before chemotherapy and then 30 minutes before breakfast, lunch and dinner on the first, second and third day after chemotherapy and each time for 30 minutes for people in this group.

Category

Placebo

3

Description

Control group: Control group: Wristbands are not used for this group. The level and severity of nausea, vomiting and comfort level of children before chemotherapy (T0), at the end of the first day (T1), at the end of the second day (T2) and at the end of the day. The third (T3) is asked and recorded by the researcher's assistant at 12:00 noon and night.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ekbatan Hospital affiliated to Hamadan University of Medical Sciences

Full name of responsible person

Fateme Mohammadi

Street address

Beginning of Ayatollah Kashani Boulevard, Hamadan University of Medical Sciences and Health Service

City

Hamedan

Province

Hamadan

Postal code

6517838698

Phone

+98 81 3334 5634

Email

mohammadifateme47@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Reza Shokoohi

Street address

Beginning of Ayatollah Kashani Boulevard, Hamadan University of Medical Sciences and Health Services

City

Hamedan

Province

Hamadan

Postal code

6517838698

Phone

+98 81 3334 5634

Email

F-mohammadi@umsha.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamedan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Private

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

Hamedan University of Medical Sciences

Full name of responsible person

Fateme Mohammadi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Beginning of Ayatollah Kashani Boulevard, Hamadan University of Medical Sciences and Health Services

City

Hamedan

Province

Hamadan

Postal code

6517838698

Phone

+98 81 3334 5634

Email
mohammadifateme47@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Fateme Mohammadi
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Beginning of Ayatollah Kashani Boulevard, Hamadan University of Medical Sciences and Health Services
City
Hamedan
Province
Hamadan
Postal code
6517838698
Phone
+98 81 3334 5634
Email
mohammadifateme47@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Fateme Mohammadi
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Beginning of Ayatollah Kashani Boulevard, Hamadan University of Medical Sciences and Health Services
City
Hamedan
Province
Hamadan
Postal code
6517838698
Phone
+98 81 3334 5634
Email
47ئخاشئشيهبشفثئث@yahoo.com

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