

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison the effect of acupressure and massage with ice on Hugo's point on pain and Physiological parameters related to chemotherapy drug injection in children with acute lymphoblastic leukemia, clinical trial

Protocol summary

Study aim

Determining and comparing the effect of acupressure and Hugo point massage with ice on pain intensity and physiological parameters induced by chemotherapy injection in children with acute lymphoblastic leukemia

Design

The clinical trial has two experimental and control groups, crossover, single blind, randomized, phase 1 on 52 patients. Four random blocks are used for randomization.

Settings and conduct

This study is performed in the blood and cancer ward of the Shahrivar Children's Educational and Medical Center in Rasht. In phase one, acupressure and ice massage interventions are performed in two groups, A and B. After one month and in the second phase, the intervention is transferred to two groups. In order to blind and prevent the effect of subjectivity on the research results, the interventions are performed by the main researcher and the consequences are measured by the researcher.

Participants/Inclusion and exclusion criteria

The study population was children 3-12 years old with acute lymphoblastic leukemia and treated with vincristine chemotherapy. Reluctance to cooperate and allergic response to chemotherapy are exclusion criteria.

Intervention groups

In phase one in the experimental group, the point of the hand Hugo where the injection is not performed, for one minute with a piece of ice (diameter 2 cm) wrapped in plastic gloves and a single layer of cotton cloth, with the fingertips, in the form of Rotate in a clockwise direction with an average pressure of 3 to 4 kg, so that the maximum pressure time of one minute and then 10 seconds of pressure is cut off and generally lasts for 5 minutes. In the acupressure group, only pressure is applied to the point. After one month of these interventions and in the second phase, the intervention

will be transferred to two groups.

Main outcome variables

Intensity of pain, Percentage arterial blood oxygen saturation, heart rate (pulse)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110122005663N2**

Registration date: **2021-11-09, 1400/08/18**

Registration timing: **prospective**

Last update: **2021-11-09, 1400/08/18**

Update count: **0**

Registration date

2021-11-09, 1400/08/18

Registrant information

Name

Mahshid Mirzaie

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3355 5056

Email address

mirzaie@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-26, 1400/09/05

Expected recruitment end date

2022-04-25, 1401/02/05

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison the effect of acupressure and massage with ice on Hugo's point on pain and Physiological parameters related to chemotherapy drug injection in children with acute lymphoblastic leukemia, clinical trial

Public title
Comparison the effect of acupressure and massage with ice on Hugo's point on pain and Physiological parameters related to chemotherapy drug injection in children with acute lymphoblastic leukemia, clinical trial

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Children aged 3-12 years With acute lymphoblastic leukemia One month has passed since the diagnosis Treated with Vincristine Chemotherapy Do not use the catheter port to prescribe chemotherapy No genetic or mental illness Organ health at the massage point Not receiving acupressure and ice massage at Hugo Point before the study Do not take painkillers 8 hours before chemotherapy injection
Exclusion criteria:
Reluctance to collaborate in the study Inadequate and severe mental and physical conditions

Age
From **3 years** old to **12 years** old

Gender
Both

Phase
N/A

Groups that have been masked
• Outcome assessor

Sample size
Target sample size: **52**
More than 1 sample in each individual
Number of samples in each individual: **2**
In the first phase of the study, one group receives ice massage intervention and the other group receives acupressure intervention. Then, after one month and in the second phase, the intervention is transferred to two groups.

Randomization (investigator's opinion)
Randomized

Randomization description
Four random blocks will be used for random assignment of samples to two groups of ice massage at Hugo point (group A) and acupressure (group B). The number of blocks required in this study is 13 blocks, based on which random allocation will be done. The sequence of random assignment of samples to two groups of ice massage at Hugo point (group A) and acupressure (group B) is determined through Random allocation online software. The sequence list of samples A and B will be kept in a

sealed envelope in the nursing office of 17 Shahrivar Hospital in Rasht. After starting the study, it will be opened by the main researcher and based on gradual referrals, children in one of groups A or B Will be located and will continue until the estimated sample size in each group is reached.

Blinding (investigator's opinion)

Single blinded

Blinding description

In order to blind the researcher and prevent the effect of mentality on the research results, acupressure and ice massage at Hugo point will be done by one of the members of the research team (main researcher) and the measurement of pain and physiological indicators will be done by the researcher.

Placebo

Not used

Assignment

Crossover

Other design features

The study method has two implementation phases. In the first phase, for group A, ice massage is performed at Hugo point and for group B, acupressure. Then, after a month of cleansing period, in the second phase, for group A, acupressure and for group B, ice massage is performed. The study is a crossover clinical trial.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Guilan University of Medical Sciences

Street address

Vice Chancellor for Research and Technology of Guilan University of Medical Sciences, in front of 17 Shahrivar hospital, Shahid Siadati Street, Namjoo Street.

City

Rasht

Province

Guilan

Postal code

4146939841

Approval date

2021-10-27, 1400/08/05

Ethics committee reference number

IR.GUMS.REC.1400.356

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

Score of pain due to chemotherapy injection

Timepoint

Before the intervention, 5 seconds before the injection and 15 seconds after the injection of chemotherapy

Method of measurement

Oucher's pain intensity self-measurement scale

2

Description

Percentage of arterial blood oxygen saturation

Timepoint

Before the intervention, 5 seconds before the injection and 15 seconds after the injection of chemotherapy

Method of measurement

Pulse oximeter device

3

Description

Heart rate(pulse)

Timepoint

Before the intervention, 5 seconds before the injection and 15 seconds after the injection of chemotherapy

Method of measurement

Pulse oximeter device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the first phase of the operation, in the intervention group, ice massage at the Hugo point is performed 5 minutes before the injection of chemotherapy by the main researcher for the child. To start the massage, first the child is placed on his back in a calm, comfortable and lying position. To determine the Hugo point, place the child's thumb in the abduction position, in which case, a prominent muscular peak (corresponding to the muscle approaching the thumb) located in the middle of the angle between the first and second bones of the palm, between the thumb and the finger. The point is on the back of the hand, the point is Hugo. Then place the hand Hugo point where the injection is not done, for one minute using a piece of ice (2 cm in diameter) wrapped in plastic gloves and a single layer of cotton cloth, using the soft part of the thumb in a rotating manner. , Press in a clockwise direction with an

average pressure of 3 to 4 kg, so that the maximum pressure time is cut off one minute at a time and then 10 seconds, and lasts for a total of 5 minutes. Then, after one month and in the second phase of the implementation, acupressure intervention will be performed for this group.

Category

Other

2

Description

Control group: In the first phase, in the control group, Hugo point acupressure is performed by the principal investigator for the child 5 minutes before the chemotherapy drug is injected. To start work, first the child is placed on his back in a calm, comfortable and lying position. To determine the Hugo point, place the child's thumb in the abduction position, in which case, a prominent muscular peak (corresponding to the muscle approaching the thumb) located in the middle of the angle between the first and second bones of the palm, between the thumb and the finger. The point is on the back of the hand, the point is Hugo. Then press the hand Hugo point where the injection is not done, with the thumb, in a clockwise direction, with a deep pressure of 3 to 4 kg, so that the maximum pressure time per time The pressure is turned off for one minute and then for 10 seconds and lasts for a total of 5 minutes. After a month and in the second phase of the performance, an ice massage intervention will be performed at Hugo Point for this group.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Children 17 Shahrivar Educational and Medical Center in Rasht

Full name of responsible person

Saeed Sadat Mansouri

Street address

17 Shahrivar Children Educational and Medical Center, in front of the south side of Shahr Park, Shahid siadati Street, Namjoo Street.

City

Rasht

Province

Guilan

Postal code

4144654379

Phone

+98 13 3336 9019

Email

dr.s.s.mansouri@gums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Mohammad Reza Naghipour

Street address

Vice Chancellor for Research and Technology of
Guilan University of Medical Sciences, in front of 17
Shahrivar hospital, Shahid Siadati Street, Namjoo
Street.

City

Rasht

Province

Guilan

Postal code

4146939841

Phone

+98 13 3333 6394

Email

naghi@gums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Rasht University of Medical Sciences

Proportion provided by this source

100

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**

Rasht University of Medical Sciences

Full name of responsible person

Mahshid Mirzaei Taklimi

Position

coach

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Shahid Beheshti School of Nursing and Midwifery,
Daneshjoo Street, Beheshti Highway

City

Rasht

Province

Guilan

Postal code

4146939841

Phone

+98 13 3355 5056

Email

mahshidmirzaie2015@gmail.com

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Rasht University of Medical Sciences

Full name of responsible person

Mahshid Mirzaei Taklimi

Position

coach

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Shahid Beheshti School of Nursing and Midwifery,
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City

Rasht

Province

Guilan

Postal code

4146939841

Phone

+98 13 3355 5056

Email

mahshidmirzaie2015@gmail.com

Person responsible for updating data

Contact**Name of organization / entity**

Rasht University of Medical Sciences

Full name of responsible person

Mahshid Mirzaei Taklimi

Position

coach

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Street address

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Daneshjoo Street, Beheshti Highway

City

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Province

Guilan

Postal code

4146939841

Phone

+98 13 3355 5056

Email

mahshidmirzaie2015@gmail.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