# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 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**
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**Name of organization / entity**

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Iran (Islamic Republic of)

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**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.

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## Sponsors / Funding sources

**1**

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**Full name of responsible person**
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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**
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**
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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