

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jun 2026

### Comparison of two methods of deep breathing and computer games on pain caused by intravenous injections in school age children with leukemia

#### Protocol summary

##### Study aim

Comparison of two methods of deep breathing and computer games on pain caused by intravenous injections in school age children with leukemia

##### Design

A randomized, double blinded clinical trial with three equal parallel groups. The sample size will be 90.

##### Settings and conduct

This double blind study Will be performed on 90 6-12 year old patients with leukemic at Dr.Sheikh Hospital in Mashhad. Blinding is done for participants, principal researcher, clinical care giver and statistician. Patients are divided into three equal groups: control, deep breathing and computer game groups.The pain in all three groups of children will be measured before and after injection and the results will be evaluated by the researcher.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosis of leukemia by oncologist at least 6 months ago; Children aged 6-12 years old; Not having acute pain; Being alert to time and place; Not using pain medications from 24 hours before injection. Non-inclusion criteria: Failure of first attempt by the nurse to inject children; Cardiovascular and respiratory disorders; Mentally retarded child; Possible child death.

##### Intervention groups

Intervention group 1: Deep breathing technique was performed by the child 1 minute before injection till 1 minute after the procedure. The pain of children was assessed by the researcher every 30 seconds using Wang-Baker pain scale. Intervention group 2: the children in the computer group played Angry Birds game then children started to play the game three minutes before the injection till to three minute after the injection.The pain of children was assessed by the researcher every 30 seconds by Wang-Baker scale. Control group: the pain of children was assessed 3

minutes before the injection till 3 minutes after it by the researcher using Wong \_ Baker Scale every 30 minutes.

##### Main outcome variables

Pain

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20171015036790N2**

Registration date: **2019-01-29, 1397/11/09**

Registration timing: **retrospective**

Last update: **2019-01-29, 1397/11/09**

Update count: **0**

##### Registration date

2019-01-29, 1397/11/09

##### Registrant information

##### Name

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51342616072

##### Email address

marsamiri@iautmu.ac.ir

##### Recruitment status

##### Recruitment complete

##### Funding source

personal

##### Expected recruitment start date

2017-11-22, 1396/09/01

##### Expected recruitment end date

2018-05-20, 1397/02/30

##### Actual recruitment start date

empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**  
Comparison of two methods of deep breathing and computer games on pain caused by intravenous injections in school age children with leukemia

**Public title**  
Effect of deep breathing and computer games on pain caused by intravenous injection in children with leukemia

**Purpose**  
Health service research

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Diagnosis of leukemia by oncologist at least 6 months ago Children aged 6-12 years old Not having acute pain during the vessel puncturing Being alert to time, place and person Need to have an intravenous line Do not use pain medications from 24 hours before the vessel is inserted At least one parent should be with child There is no problem for handheld computer games Lack of mental retardation

**Exclusion criteria:**  
Children in whom first attempt has been failed by the nurse Cardiovascular and respiratory disorders not cooperating child Mentally retarded child Possible child death

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

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor

**Sample size**  
Target sample size: **90**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Patients are divided into one of the deep breathing intervention groups (A), computer-controlled intervention (B) and control (C) by lottery.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
The study is double blind , so that the participants, principal researcher, clinical care giver and data analyzer are not aware of the allocation of the patients.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Islamic Azad University of Medical Sciences of Tehran

##### Street address

Islamic Azad University Medical Sciences of Tehran, Khaghani Avenue, Shariati St.

##### City

Tehran

##### Province

Tehran

##### Postal code

1916893813

#### Approval date

2017-11-07, 1396/08/16

#### Ethics committee reference number

IR.IAU.TMU.REC.1396.183

## Health conditions studied

### 1

#### Description of health condition studied

Acute lymphoblastic leukaemia

#### ICD-10 code

C91.0

#### ICD-10 code description

Acute lymphoblastic leukaemia [ALL]

## Primary outcomes

### 1

#### Description

pain

#### Timepoint

In the intervention group with deep breathing, the child's pain will be measured from 1 minute before the incision until 1 minute after the incision every 30 seconds. In the intervention group with computer games, the child's pain will be measured from 3 minutes before the incision until 3 minutes after the incision every 30 seconds. In the control group, the child's pain will be measured from 3 minutes before the incision until 3 minutes after the incision every 30 seconds.

#### Method of measurement

Vang-Baker pain measurement scale

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

First intervention group: 30 children are randomly allocated to this group. Then Hey\_Hu technique is taught to the patients before injection. In this method, at first the child takes a deep breath, exhales while exhales whispering hey. Then he/she inhales deeply again and exhales whispering hu. This is practiced by the child in the order to implement it accurately and is performed 1 minute before till 1 minute after the procedure. The pain of children will be assessed by Wong\_Baker Pain Measurement Scale every 30 seconds by the researcher.

#### Category

Prevention

### 2

#### Description

Second intervention group: In this group, 30 children are randomly allocated. The children in the hand-held computer group play Angry Birds game. Then children start to play the game 3 minutes before the injection till 3 minutes after the procedure. The pain of children will be assessed by Wong\_Baker pain Measurement Scale every 30 second by the researcher.

#### Category

Prevention

### 3

#### Description

Control group: In this group, 30 children are randomly allocated. Then the nurse does the injection through routine procedure. The pain of children will be assessed 3 minutes before the injection till 3 minutes after the injection by Wong\_Baker Pain Measurement Scale every 30 second by the researcher.

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Dr. Sheikh Hospital

##### Full name of responsible person

Mersa Sadat Miri

##### Street address

Dr. Sheikh Children's Hospital, Taheri Street, Tohid square

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9139963185

##### Phone

+98 51 3726 9021

##### Fax

##### Email

Sheikh.Hos@mums.ac.ir

##### Web page address

<http://sheikh.mums.ac.ir/>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Islamic Azad University

##### Full name of responsible person

Dr. Bijan Ranjbar

##### Street address

Seventh Floor, Third Block, Central building of Islamic Azad University, Daneshgah square, Shohaday Hesarak blvd

##### City

Tehran

##### Province

Tehran

##### Postal code

1916893813

##### Phone

+98 21 2200 6660

##### Fax

##### Email

info@rvp.iau.ir

##### Web page address

<http://www.rvp.iau.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

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

Islamic Azad University

##### Full name of responsible person

Mersa sadat Miri Jagharq

##### Position

Nurse

##### Latest degree

Bachelor

**Other areas of specialty/work**

**Street address**

No 130, Behvarz 4, Janbazan Blvd

**City**

Neyshabour

**Province**

Razavi Khorasan

**Postal code**

9193863397

**Phone**

+98 51 4261 6072

**Fax**

**Email**

marsamiri@iautmu.ac.ir

**Web page address**

**Street address**

No 130, Behvarz 4, Janbazan Blvd

**City**

Neyshabour

**Province**

Razavi Khorasan

**Postal code**

9193863397

**Phone**

+98 51 4261 6072

**Fax**

**Email**

marsamiri@iautmu.ac.ir

**Web page address**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Tehran Medical Branch, Islamic Azad University

**Full name of responsible person**

Fatemeh Alaei Karahroodi

**Position**

P.H.D

**Latest degree**

Medical doctor

**Other areas of specialty/work**

**Street address**

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

**City**

Tehran

**Province**

Tehran

**Postal code**

1916893813

**Phone**

+98 21 2200 6660

**Fax**

**Email**

falaekarahroudy@yahoo.com

**Web page address**

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Mersa Sadat Miri Jagharq

**Position**

Nurse

**Latest degree**

Bachelor

**Other areas of specialty/work**

**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**

Yes - There is 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

**Title and more details about the data/document**

This form contains questions about the degree of childbirth, the duration of the disease, the frequency of admission, the type of cancer, the organs used, the vein used, for example, metacarpal, cephalic, acyclic, intravenous injection, angioquist size, maternal education.

**When the data will become available and for how long**

Start the access period 6 months after printing the results

**To whom data/document is available**

For researchers, doctors, nurses

**Under which criteria data/document could be used**

All the medical staffs

**From where data/document is obtainable**

Address: Dr.Sheikh hospital, Taheri St, Tohid Sq.  
Mashhad Tel: +985137269021-5

**What processes are involved for a request to access data/document**

Upon request, by e-mail at most one week

**Comments**