

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