Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Nov 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
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Fax
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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
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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
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Province
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Postal code
9193863397
Phone
+98 51 4261 6072
Fax
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marsamiri@iautmu.ac.ir
Web page address

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