

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

The impact of pain management education on acute pain severity in children (5-12y/o) with leukemia undergoing bone marrow aspiration in imam reza's hospital in Shiraz, Iran in 2012-2013

Protocol summary

Summary

Designate the effect of pain management on acute pain in the pediatrics between 5-12 years old that have leukemia under bone marrow aspiration which go to imam reza's hospital in Shiraz, Iran. Studying involves two groups (case and control). Population of studying: the pediatrics in the age between 5-12 that have leukemia under bone marrow aspiration. Sample's volume: 60 persons; at first, samples on the base of having the conditions for entering in study and select an easy method for sampling and after explaining the goal of study, take letting form; then the volunteers are divided in two groups in suddenly devotion method. The searcher in the time of studying will be present in that place. In this step each group will be under general case. Later, 30 and 60 minutes after doing the procedure the strength of pain by use of questionnaire for all volunteers will be determined the group of case and control. At the end, an informant booklet about disease and pediatric's pain management will give to their parents for studying during the first and the second aspiration. Then the date and the time of educational classes will be determined. Educational plan includes four section, 45 minutes theoretical and practical classes that contain speaking, practical and group's speaking which be done in groups with ten members for 4 weeks. Then the date and the time of second bone marrow aspirations will announced for the pediatrics and their parents. Then the doctor will do the aspiration. 30 and 60 minutes after doing the procedure the number of pain severity with pain questionnaire for two groups, case and control, will be determined.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013011512121N2**

Registration date: **2014-07-17, 1393/04/26**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-07-17, 1393/04/26

Registrant information

Name

Marziyeh Kargar Jahromi

Name of organization / entity

Fatemeh Holiness Nursing and Midwifery College

Country

Iran (Islamic Republic of)

Phone

+98 71 1647 4254

Email address

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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2012-10-11, 1391/07/20

Expected recruitment end date

2013-08-06, 1392/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The impact of pain management education on acute pain

severity in children (5-12y/o) with leukemia undergoing bone marrow aspiration in imam reza's hospital in Shiraz, Iran in 2012-2013

Public title

The impact of pain management education on acute pain severity in children (5-12y/o) with leukemia undergoing bone marrow aspiration

Purpose

Supportive

Inclusion/Exclusion criteria

inclusion criteria:the age of pediatric should be between 5 to 12 years old;peditrics doesn't receive the pain management schedule;parents should fill letting form consciously and wants parents to seek the peditrics idea in the procedure;the patient can do his/her exercise with diagnose of procedure doctor;6-peditrics doesn't have any chronic disease. Exclusion criteria: peditrics or parents don't want to continue the project;unable to continue the exercise;absense in the educational class more than one time;the peditrics needs to be in the hospital during the intervention.

Age

From **5 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee Of Shiraz University Of Medical Science

Street address

Shiraz University of Medical Science,Zand Ave.,Shiraz,Iran

City

Shiraz

Postal code

14336-71348

Approval date

2012-12-13, 1391/09/23

Ethics committee reference number

CT-91-6340

Health conditions studied

1

Description of health condition studied

Pain

ICD-10 code

R52.0

ICD-10 code description

Acute Pain

Primary outcomes

1

Description

Pain

Timepoint

Before intervention, 2 month after intervention and in both stage before, 30 and 60 minute after doing procedure

Method of measurement

Oucher scale

Secondary outcomes

empty

Intervention groups

1

Description

in case group education is about desease,medical management of pain and non medical management of pain that contain distraction,relaxation.this contain educate to patient in 4 section in 1 month and a educational book give to them.in control group we don't anything of this and in the end of the investigation all of this contaain educate to control group

Category

Behavior

2

Description

in control group we don't anything of this(distraction,relaxation &educational book don't give to them and in the end of the investigation all of this contaain educate to control group

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Poly Clinic

Full name of responsible person

Marziyeh Kargar

Street address

Imam Reza Poly Clinic, Namazi Square, Shiraz, Iran

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Shiraz University Of Medical Science

Full name of responsible person

Gholamreza Hatam

Street address

Shiraz University Of Medical Sciences, Zand st., Shiraz, Iran

City

Shiraz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for Research, Shiraz University Of Medical Science

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

School Of Nursing and Midwifery

Full name of responsible person

Marziyeh Kargar

Position

Master of Nursing/Faculty Member

Other areas of specialty/work

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Person responsible for updating data

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Graduate Student

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report

empty
Analytic Code
empty
Data Dictionary
empty