

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Effectiveness of Regular Breathing Technique (He-Hu) on Reduction of Intrathecal Injection Pain in Leukemic Children: A Randomized Clinical Trial

Protocol summary

Summary

Children with chronic diseases such as leukemia are subjected to pain during various procedures. Distraction is one of the easiest and least costly methods of non-pharmacological pain relief that has not been paid attention to by nurses. In the present study, the effectiveness of regular breathing method (hey-hu) in reduction of pain of intrathecal injection in leukemic children is evaluated. This study is conducted as a single blind randomized clinical trial among 100 patients coming to Shahid sadoughi Hospital, Yazd, Iran. The patients are 6-15 years old children coming to oncology ward suffering from leukemia. They are selected and randomly allocated to either regular breathing group or control group in equal numbers. The pain of children is assessed by Wong pain face scale.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012102311230N1**
Registration date: **2012-12-23, 1391/10/03**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-12-23, 1391/10/03

Registrant information

Name

Zahra Pourmovahed

Name of organization / entity

Shahid Sadoughi University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 35 3824 1751

Email address

z_pourmovahed@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Sadoughi University of Medical Sciences, Yazd, Iran

Expected recruitment start date

2010-10-12, 1389/07/20

Expected recruitment end date

2012-03-10, 1390/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of Regular Breathing Technique (He-Hu) on Reduction of Intrathecal Injection Pain in Leukemic Children: A Randomized Clinical Trial

Public title

Effectiveness of Regular Breathing Technique (He-Hu) on Reduction of Intrathecal Injection Pain

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: alertness, verbal, subjective, visual and hearing ability; absence of pain and physiological needs (thirst, need for excretion....) before injection. The patients were 6-15 years old children coming to oncology ward suffering from leukemia. Exclusion criteria: Those patients who had a second injection were excluded from the study. We also excluded patients who had any

respiratory difficulties.

Age
From **6 years** old to **15 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shahid Sadoughi University of Medical Sciences

Street address
Shahid Sadoughi University of Medical Sciences,
Bahonar square

City
Yazd

Postal code

Approval date
2010-03-15, 1388/12/24

Ethics committee reference number
118120

Health conditions studied

1

Description of health condition studied
Blood cancer

ICD-10 code
C40-C41

ICD-10 code description
Malignant neoplasms of bone and articular cartilage

2

Description of health condition studied
Diseases of the blood

ICD-10 code
D50-D89

ICD-10 code description

Diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism

Primary outcomes

1

Description
Pain

Timepoint
Immediately after intervention

Method of measurement
Wong pain face scale

Secondary outcomes

empty

Intervention groups

1

Description
The He-Hu technique was demonstrated to the subjects before injection in the study group which was as follows: The child was asked to initially inhale deeply and utter 'He; while exhaling. Then the child was asked to inhale deeply again and utter 'Hu' while exhaling. This method was practiced with the child in order to implement it accurately and was performed one minute before procedure till the end of the procedure. A respiratory rate of 20-30 per minute was considered for the children.

Category
Other

2

Description
There is not any intervention

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Sadoughi Hospital

Full name of responsible person
Zahra Pourmovahed

Street address
Shahid Sadoughi University of Medical Sciences,
Bahonar square

City
Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Fateme Ezadini Ardekani

Street address

Shahid Sadoughi University of Medical Sciences, Bahonar square

City

Yazd

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shahid Sadoughi University of Medical Sciences

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**

Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Zahra Pourmovahed

Position

master of sciences

Other areas of specialty/work**Street address**

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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