Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigate Effect Of Snoezelen Room On Pain In Patient With Acute Lymphobelastic Leukemia Under Lumbar Puncture

Protocol summary

Summary

This study is a semi-experimental clinical trial to determine the effect of Snoezelen room on pain intensity caused by lumbar puncture in children with acute lymphoblastic leukemia. The study samples include 47 children with acute lymphoblastic leukemia admitted to Ali-Asghar Children’s Hospital and Children's Medical Center which are selected according to the inclusion criteria (age of 4 to 12 years, undergoing lumbar puncture (LP) or intrathecal chemotherapy (IT), lack of mental disability, lack of use of local anesthesia) and the exclusion criteria (use of narcotic, analgesics, tranquillizers during the procedure) and by an easy or available sampling method and divided into two groups of 74 patients of control and test. In the test group, (LP) or (IT) is done at Snoezelen room for 15 to 30 minutes where includes the aquarium, displaying luminous images by the light dancing device on the walls, essential oil burner containing two to five drops of geranium essential oil, 100% playing relaxing music and squeezing the sponge balls to stimulate the sense of touch. After the procedure, according to the child's age and literacy, will be asked him to select and express the rate of his pain intensity numerically or by images. The rate of pain intensity is checked by using the "Scale Pain Oucher" tool. In the control group of the procedure, (IT) (or (LP) is done in typical rooms. The primary outcome of study is reduction in pain intensity of lumbar puncture procedure in children with acute lymphoblastic leukemia

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016021326528N1**
Registration date: **2017-02-16, 1395/11/28**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2017-02-16, 1395/11/28

Registrant information

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2016-06-30, 1395/04/10

Expected recruitment end date

2017-07-01, 1396/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigate Effect Of Snoezelen Room On Pain In Patient With Acute Lymphobelastic Leukemia Under Lumbar Puncture

Public title

Effect Of Snoezelen Room On Pain

Purpose

Treatment

Inclusion/Exclusion criteria
(Inclusion criteria: Age of children be 4 to 12; Children be with acute lymphoblastic leukemia (ALL) who undergo a lumbar puncture or intrathecal chemotherapy; Not have the ability to smell. (Not be suffering from a bad cold); Not have any mental disabilities; Not have the other chronic diseases such as diabetes; Not have any visual impairments; Not have any hearing problems; Not used any Local anesthesia; Not be with asthma or allergies to herbal essences; Exclusion criteria: Narcotic, analgesics, tranquilizers and sleeping pills be used during the procedure) .
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Other
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Iran University Of Medical Siencs
Street address
Tehran. Milad Tower
City
Tehran
Postal code
Approval date
2016-04-02, 1395/01/14
Ethics committee reference number
IR.IUMS.REC.9211196220

Health conditions studied

1

Description of health condition studied
Acute lymphobelastic Leukemia
ICD-10 code
C91.0
ICD-10 code description
Acute lymphoblastic leukaemia [ALL]

Primary outcomes

1

Description
Pain
Timepoint
After intervention
Method of measurement
Oucher pain scale

Secondary outcomes

1

Description
Without Sideffects
Timepoint
After Intervention
Method of measurement
Whithout Scale

Intervention groups

1

Description
In intervention group lumbar puncture carry out in Snoezelen room.
Category
Other

2

Description
In control group lumbar puncture carry out in routine room.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Children's Medical Ceter
Full name of responsible person
Sodabeh Hassani
Street address
Dr Qarib St
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University Of Medical Sienecs
Full name of responsible person
Parvizy Soroor
Street address
Tehran Vanak St
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran University Of Medical Sienecs
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
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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