

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

The effects of reflexology on pain and physiological indexes due to intrathecal (IT) chemotherapy drugs in children with cancer

Protocol summary

Study aim

The effect of reflexology on pain intensity and physiological indexes due to intrathecal chemotherapy drugs in children with cancer.

Design

The study conducted as randomized clinical trial, with control group and single-blinded. The sample size included 70 subjects (35 the intervention group) and (35 the control group). The selection of two groups is based on lottery method.

Settings and conduct

This study conducted as single-blind in the Pediatric Hematology Department. In the intervention group, after controlling injection of intrathecal chemotherapy, the physiologic indexes and pain examined for 20 minutes before injection by the co-researcher. The foot massage conducted in two legs for 20 minutes by the researcher. While done intrathecal chemotherapy, pain and physiological indexes are investigated again by the co-researcher.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Having leukemia and have intrathecal chemotherapy drugs order, Having no seizure or any emergency disorders, Have not received any sedation and analgesic drugs before intervention, Have not received any foot-reflexology. Exclusion criteria: Not collaborating of child or family, Having physical disorders.

Intervention groups

Intervention group: Before injection of intrathecal chemotherapy drug, physiological indexes were checked. Then, a general massage and then a appropriative massage on the two-foot reflection points is performed for 20 minutes, ie10 minutes for each foot, , during a session immediately before the intrathecal injection. During the injection of the intrathecal chemotherapy drug, the physiological indexes and pain were examined. Control group: without reflexology, the physiological indexes and pain are examined for the same times.

Main outcome variables

Pain; physiological indexes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20121025011261N3**

Registration date: **2020-03-07, 1398/12/17**

Registration timing: **retrospective**

Last update: **2020-03-07, 1398/12/17**

Update count: **0**

Registration date

2020-03-07, 1398/12/17

Registrant information

Name

Alia Jalalodini

Name of organization / entity

Nursing and Midwifery College

Country

Iran (Islamic Republic of)

Phone

+98 54 1244 2481

Email address

jalalodini@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-02, 1398/03/12

Expected recruitment end date

2019-11-03, 1398/08/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effects of reflexology on pain and physiological indexes due to intrathecal (IT) chemotherapy drugs in children with cancer

Public title
The effects of foot- reflexology on pain and physiological indexes due to intrathecal (IT) chemotherapy drugs

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Having leukemia and have intrathecal chemotherapy drugs order. Having no seizure or any emergency disorders. Have not received any sedation and analgesic drugs before intervention. Have not received any foot-reflexology.
Exclusion criteria:
 - Not collaborating of child or family - Having physical disorders

Age
From **6 years** old to **12 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
Samples divided randomly into two groups; intervention group and control group. As, envelopes containing cards with numbers one and two are given to the participants, if the number one is chosen, they will be assigned to the intervention group. Otherwise they will be assigned to the control group.

Blinding (investigator's opinion)
Single blinded

Blinding description
The completion of questionnaires and the investigation of physiological indexes implemented by the researcher who, unawares of the allocation of the groups before and during intervention.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zahedan University of Medical Sciences

Street address

Zahedan University of Medical Sciences, Janat Blvd

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816745477

Approval date

2019-08-11, 1398/05/20

Ethics committee reference number

IR.ZAUMS.REC.1398.169

Health conditions studied

1

Description of health condition studied

Pain

ICD-10 code

G89.1

ICD-10 code description

Acute pain, not elsewhere classified

2

Description of health condition studied

لوسمی حاد

ICD-10 code

C90.1

ICD-10 code description

Plasma cell leukemia

Primary outcomes

1

Description

The pain

Timepoint

20 minutes before and during injection of chemotherapy.

Method of measurement

The ouchers scale

2

Description

Systolic and diastolic blood pressure

Timepoint

20 minutes before, and during intratechal injection of chemotherapy.

Method of measurement

Mercury pressure device with APK2 brand.

3

Description

Pulse

Timepoint

20 minutes before, and during intrathecal injection of chemotherapy.

Method of measurement

The watch with mark Orient

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 20 minutes before injection of intrathecal chemotherapy drug, physiological indexes were checked. Then, a general massage and then a appropriative massage on the two-foot reflection points is performed for 20 minutes, ie10 minutes for each foot, , during a session immediately before the intrathecal injection. During the injection of the intrathecal chemotherapy drug, the physiological indexes and pain were examined.

Category

Treatment - Other

2

Description

Control group: without reflexology, the physiological indexes and pain are examined in the determined times.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali Abne Abitaleb Hospital related to Zahedan University of Medical Sciences and Health Services

Full name of responsible person

Alia Jalalodini

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Ali Abne Abitaleb Hospital, Health Blvd, Persian Gulf Highway, Zahedan

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zahedan University of Medical Sciences

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

Zahedan University of Medical Sciences

Full name of responsible person

Alia Jalalodini

Position

Faculty member of science, Master of science in nursing,

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for updating data

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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

Undecided - It is not yet known if there will be 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