

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

The effect of foot reflexology massage on vital signs and anxiety Following injection of chemotherapy drug in pediatric 6-12 years old in Kerman Afzalipour Hospital Oncology Center in 2015

Protocol summary

Summary

The objective of this study is to determine the Effect of reflexology massage on vital signs and anxiety of pediatric undergoing chemotherapy. In this quasi-experimental study between February 2014 to July 2015 in Kerman Afzalipour Hospital Oncology Center, 120 pediatric Between 6 to 12 years with Leukemia are eligible to participate in the study, Selected by sampling method and then are randomly blocks allocated into three groups Intervention, placebo and control. The study is a single blind and Fellow researcher who performs the data collection is unaware of the assigned groups. The pediatric in the Intervention group receive foot reflexology massage for 20 minutes immediately before injection chemotherapy, In the placebo group receive foot simple touch for 20 minutes immediately before injection chemotherapy, while control group does not receive any intervention. Anxiety level (Observational Scale Behavior Disress- Rare) and vital signs are measured in both groups Intervention and placebo immediately before intervention and immediately after injection is measured. In the control group 20 minutes before and immediately after the injection, vital signs form and anxiety questionnaire is completed until the effects of time in all groups be controlled. The form of individual characteristics before the study was completed in three groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014110919862N1**

Registration date: **2016-03-01, 1394/12/11**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-03-01, 1394/12/11

Registrant information

Name

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Name of organization / entity

Kerman University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Approved project of Kerman University of Medical Science Research and Technology Centre with number 93/558

Expected recruitment start date

2015-01-28, 1393/11/08

Expected recruitment end date

2015-07-01, 1394/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of foot reflexology massage on vital signs and anxiety Following injection of chemotherapy drug in pediatric 6-12 years old in Kerman Afzalipour Hospital Oncology Center in 2015

Public title

The effects of foot reflexology massage on vital signs and anxiety pediatric undergoing chemotherapy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Having aged between 6 to 12 years; having a case in Kerman Oncology Center; having leukemia; Using the same chemotherapy drug; Having a member's health in the legs; No history of foot reflexology. Exclusion criteria: Having physical problems (Verbal, Visual, Mental, Hearing); using of Anti-Anxiety drugs.

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kerman University of Medical Sciences

Street address

Kerman, Crossroads Tahmasebabad, Kerman
University of Medical Sciences Research and
Technology Centre

City

Kerman

Postal code

76177

Approval date

2015-02-20, 1393/12/01

Ethics committee reference number

k/93/537

Health conditions studied

1

Description of health condition studied

Leukemia

ICD-10 code

C91, C92,

ICD-10 code description

Lymphoid leukaemia, Myeloid leukaemia, Monocytic leukaemia, Other leukaemias of specified cell type, Leukaemia of unspecified cell type

2

Description of health condition studied

Chemotherapy

ICD-10 code

Z50, Z51

ICD-10 code description

Care involving use of rehabilitation procedures, Other medical care

Primary outcomes

1

Description

Anxiety

Timepoint

Immediately before the intervention and immediately after injection of chemotherapy

Method of measurement

Observational Scale behavior Disress- Rare

2

Description

Systolic blood pressure

Timepoint

Immediately before the intervention and immediately after injection of chemotherapy

Method of measurement

The using of mercury manometers in terms of millimeters of mercury

3

Description

Diastolic blood pressure

Timepoint

Immediately before the intervention and immediately after injection of chemotherapy

Method of measurement

The using of mercury manometers in terms of millimeters of mercury

4

Description

Pulse

Timepoint

Immediately before the intervention and immediately after injection of chemotherapy

Method of measurement

Radial pulse count based on the number of minutes

5

Description

Respiratory Rate

Timepoint

Immediately before the intervention and immediately after injection of chemotherapy

Method of measurement

Counting up and down movements of the chest in terms of number of minutes

6

Description

Temperature

Timepoint

Immediately before the intervention and immediately after injection of chemotherapy

Method of measurement

Axillary thermometers in degrees Centigrade

Secondary outcomes

1

Description

Patient satisfaction

Timepoint

During the intervention and during chemotherapy drug injection

Method of measurement

The question of research units

Intervention groups

1

Description

In the intervention group: Foot reflexology massage for 20 minutes before the injection of chemotherapy drug in the intervention group, that conducted by researcher. That first relaxation Foot massage is done for 2 minutes and then foot reflexology massage for 8 minutes is reflected around the big toe and attention to four points, including solar plexus, pituitary, heart and liver, which in the middle of the foot, placed the massage. The massage is done with Baby oil that is not curative, just for lubrication and convenience. Each foot reflexology points with using the middle part of the first paragraph of index finger and thumb and the fleshy part of the thumb researchers, with constant pressure to the 0/5 cm and in the event that a third of white nail bed, without interruption fingers the skin of the feet, the massage is assigned in the form of era. Foot reflexology massage for every foot is 10 minutes and takes 20 minutes total for both legs. This intervention done for patients in outpatient oncology center in Kerman. In the before intervention Preparations are will be given to the samples (A full description of intervention, Time Intervention, Time and manner chemotherapy, Allowing

the patient to express feelings, Asking questions and Responding to questions asked by patients)

Category

Other

2

Description

In the control group over the 20 minutes before the injection of chemotherapy medications no action was taken

Category

Other

3

Description

In the placebo group: Do a simple touch of the foot for 20 minutes before the injection of chemotherapy drug in the placebo group, that conducted by researcher. The simple touch for every foot is 10 minutes and takes 20 minutes total for both legs. This intervention done for patients in outpatient oncology center in Kerman. In the before intervention Preparations are will be given to the samples (A full description of intervention, Time Intervention, Time and manner chemotherapy, Allowing the patient to express feelings, Asking questions and Responding to questions asked by patients)

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Kerman Afzalipoor Hospital Oncology Center

Full name of responsible person

Akram Ghazavi

Street address

Kerman, Imam Khomeini Highway, Hospital Afzalipoor Children's Oncology Center

City

Kerman

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-Chancellor for Research, Kerman University of Medical Sciences

Full name of responsible person

Dr Abbas Pardakhti

Street address

Kerman, Crossroads Tahmasb Abad, Kerman Vice-Chancellor for Research, Kerman University of Medical Sciences

City

Kerman

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, Kerman 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

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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