Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 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
Sakine Sabzevari
Name of organization / entity
Kerman University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 34 3132 5219
Email address
s_sabzevari@kmu.ac.ir

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 Afzalipour 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
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
sakineh sabzevari
Position
Students Master of Nursing
Other areas of specialty/work
Street address
Kerman, The beginning of the Haft Baghe Alavi Road, Kerman University of Medical Sciences Campus, School of Razi Nursing and Midwifery
City
Kerman
Postal code
76177
Phone
+98 34 3131 5219
Fax
+98 34 3131 5218
Email
aghazavi114@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Sakineh Sabzevari
Position
Assisstant professor,Faculty member
Other areas of specialty/work
Street address
Kerman, The beginning of the Haft Baghe Alavi Road, Kerman University of Medical Sciences Campus, School of Razi Nursing and Midwifery
City
Kerman
Postal code
76177
Phone
+98 34 3131 5219
Fax
+98 34 3131 5218
Email
S_Sabzevari@kmu.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Sakineh Sabzevari
Position
Assisstant professor/ Faculty member
Other areas of specialty/work
Street address
Kerman, The beginning of the Haft Baghe Alavi Road, Kerman University of Medical Sciences Campus, School of Razi Nursing and Midwifery
City
kerman
Postal code
76177
Phone
+98 34 3131 5219
Fax
+98 34 3131 5218
Email
S_Sabzevari@kmu.ac.ir
Web page address

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