Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

comparison the effect of acupressure in the Pericardium 6 (pc6) &ʼ Shenmen (HT7) points & foot reflexology on sleep habits disorder children with leukemia under chemotherapy

Protocol summary

Study aim

The aim of this study was to comparison the effect acupressure and reflexology on sleep habits disorder in children with leukemia under chemotherapy

Design

Design of study: A randomized , with parallel group, not blinded, with controlled group; Society studied is 60 children with leukemia under chemotherapy Hospitalization in the Doctor Sheikh hospital of Mashhad.

Settings and conduct

The study is done at Doctor Sheikh Hospital in Mashhad, Iran. Sampling were available and assigned to the study groups using stratified random time blocks method

Participants/Inclusion and exclusion criteria

Inclusion criteria: children aged 6-12 years with leukemia, no previous at treatment sessions of complementary medicine such as reflexology, relaxation & massage methods for last 6 month, not being foot palm inflammation, infection lack of ulcer and fracture at the pressure points, none congenital disorders having sleep disorder higher than 41 on The Children's Sleep Habits Questionnaire (CSHQ). Exclusion criteria: Patient’s unwillingness to continue the collaboration in this study

Intervention groups

Three group. receiving accupressure receiving reflexology and control group In the intervention group accuprssure massage will be conducted on the pc6 , HT7 points for 3 day , day by day within 1 week In the intervention group reflexology massage will be conducted on the Foot thumb for 3 day , every other day within 1 week The control group did not receive any intervention other

Main outcome variables

sleep habits disorder

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171115037481N2**
Registration date: **2018-06-23, 1397/04/02**
Registration timing: **retrospective**

Last update: **2018-06-23, 1397/04/02**
Update count: **0**

Registration date

2018-06-23, 1397/04/02

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3452 4555

Email address

rezaeiz951@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-23, 1396/10/02

Expected recruitment end date

2018-05-05, 1397/02/15

Actual recruitment start date

2017-12-23, 1396/10/02

Actual recruitment end date

2018-03-20, 1396/12/29

Trial completion date

empty

Scientific title
comparison the effect of acupressure in the Pericardium 6 (pc6) &ʺShenmen (HT7) points & foot reflexology on sleep habits disorder children with leukemia under chemotherapy

Public title
comparison the effect of acupressure & reflexology on sleep habits disorder leukemia

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
children aged 6-12 years with leukemia no previous at treatment sessions of complementary medicine such as reflexology, relaxation & massage methods for last 6 month not being foot palm inflammation or infection lack of ulcer and fracture at the pressure points do not use hypnotics experience at least one course of childhood treatment with chemotherapy permitted by doctor none congenital disorders having sleep disorder higher than 41 on The Children's Sleep Habits Questionnaire (CSHQ)

Exclusion criteria:
Patient’s unwillingness to continue the collaboration in this study

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: **60**
Actual sample size reached: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
The research units according to the sequences that generated by SPSS software before the start of the study were randomly divided into Reflexology and Accuprressure intervention and control groups

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethic committee of Mashhad university of medical siences

Street address
Ghoreishi building.daneshgah street.

City
Mashhad

Province
Razavi Khorasan

Postal code
9138813944

Approval date
2017-12-23, 1396/10/02

Ethics committee reference number
IR.MUMS.REC.1396.319

Health conditions studied

1

Description of health condition studied
Leukemia

ICD-10 code
C95

ICD-10 code description
Leukaemia of unspecified cell type

Primary outcomes

1

Description
sleep habits disorder

Timepoint
At beginning the study and one week later

Method of measurement
Questionarre children's sleep habits CSHQ

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: accupressure . In the intervention group accuprssure massage will be conducted on the pc6 , HT7 points for 3 day, every other day, within 1 week.

Category
Treatment - Other

2

Description
Intervention group: reflexology. In the intervention group reflexology massage will be conducted on the Foot thumb for 3 day, every other day, within 1 week

Category
Treatment - Other

3

Description
Control group: no intervention
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Mashhad Doctor Sheikh hospital
Full name of responsible person
Dr Zahra Badee
Street address
Doctor Sheikh Hospital, Tohid Square, Motahari Avenue
City
Mashhad
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917351358
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+98 51 3726 9021
Email
Shaikh.hospital@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr Mohsen Tafaghodi
Street address
Ghoreishi building. Daneshgah street.
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91735951
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vcresearch@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Zeinab Rezaei
Position
Nursing Master
Latest degree
Bachelor
Other areas of specialty/work
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Person responsible for updating data

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Contact

Name of organization / entity
Mashhad University of Medical Sciences

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Zeinab Rezaei

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Email

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
Not applicable