Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparing the effect of acupressure on the SP6 point and foot reflexology on sleep quality and fatigue in patients with lukemia hospitalized in Imam khomeini Hospital in Urmia in 2022

Protocol summary

Study aim
Determining and comparing the effect of acupressure and foot reflexology massage on the quality of sleep and fatigue of leukemia patients admitted to Imam Khomeini Hospital Urmia in 1401

Design
A controlled, parallel-group, single-blind, randomized, phase 3 clinical trial on 102 patients. For randomization, cards (a), (b) and (c) were used.

Settings and conduct
This study is a single blind clinical trial research with a pre-test-post-test design. It will be implemented in Urmia University of Medical Sciences, Urmia Imam Khomeini Hospital

Participants/Inclusion and exclusion criteria
Consent of patients to participate in the study suffering from chronic lymphoid leukemia Age above 18 years and less than 80 years Ability to speak Persian

Intervention groups
In the acupressure group, in parallel with these routine cares, acupressure will be performed for each sample using the SP6 point for four weeks and every day (5 minutes) by the researcher. It should be mentioned that the researcher had personally attended all the necessary training related to acupressure and foot massage therapy from the complementary medicine specialist of Urmia University of Medical Sciences (Dr. Nozad; head of the Iranian Complementary Medicine Association) and received the necessary certificate. has done (appendix). In the foot massage therapy group, the intervention will be such that for the patients of this intervention group, after preparing the patient and greasing the soles of the feet with sweet almond oil, which is used for cold and wetness for all temperaments, every day for four consecutive weeks Reflexology is performed for 5 minutes on the treatment points on the soles of both feet. No intervention will be done in the control group and they will only receive routine ward care.

Main outcome variables
quality of sleep and fatigue of patients

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190127042512N2**
Registration date: **2023-02-18, 1401/11/29**
Registration timing: **prospective**

Last update: **2023-02-18, 1401/11/29**
Update count: **0**

Registration date
2023-02-18, 1401/11/29

Registrant information

Name
Rasoul Goli

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 44 4853 3530

Email address
rasoulgoli94@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-03-01, 1401/12/10

Expected recruitment end date
2023-03-30, 1402/01/10

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the effect of acupressure on the SP6 point and foot reflexology on sleep quality and fatigue in patients with lukemia hospitalized in Imam khomeini Hospital in Urmia in 2022

Public title
he effect of acupressure on the SP6 point and foot reflexology on sleep quality and fatigue in patients with lukemia
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Consent of patients to participate in the study Conscious and oriented patients with stable health status Suffering from chronic lymphoid leukemia Age above 18 years and less than 80 years Ability to speak Persian
Exclusion criteria:
Having chronic diseases such as diabetes, cardiovascular and respiratory diseases Having mental disorders receiving radiotherapy Having an injury or surgery on the sole of the foot
Age
From **18 years** old to **80 years** old
Gender
Both

Phase
3
Groups that have been masked

- Data analyser

Sample size
Target sample size: **102**
Randomization (investigator's opinion)
Randomized
Randomization description
The selected samples will be divided into two intervention groups and one control group using simple random sampling method. The method of random allocation into three groups was done by taking the cards (a), (b) and (c) by the patients, and the researcher divided the samples into three groups using the cards (a), (b) and (c). Acupressure, sole reflex massage and control will be divided. In this way, the patients who were included in the study, if card (a) is removed, will be included in the acupressure group, card (b) will be included in the sole reflex massage group, and card (c) will be included in the control group.
Blinding (investigator's opinion)
Single blinded
Blinding description
Blinding in this study is single blind, so that the statistician is not aware of the study groups and the data analyst is not aware of which data are related to the intervention group and which data are related to the control group.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics committee of Urmia University of Medical Sciences
Street address
Urmia, Resalat Blvd, Emergency Alley
City
Urmia
Province
West Azarbaijan
Postal code
5714783734
Approval date
2022-11-08, 1401/08/17
Ethics committee reference number
IR.UMSU.REC.1401.296

Health conditions studied

1

Description of health condition studied
Malignant neoplasms, stated or presumed to be primary, of lymphoid, haematopoietic and related tissue
ICD-10 code
C81-C96
ICD-10 code description
Malignant neoplasms, stated or presumed to be primary, of lymphoid, haematopoietic and related tissue

Primary outcomes

1

Description
Sleep quality score In Pittsburgh Sleep Quality Index (PSQI)
Timepoint
Measurement of sleep quality score before the intervention and one month after the intervention
Method of measurement
Pittsburgh Sleep Quality Index (PSQI)

2

Description
Fatigue score of Cancer Fatigue Scale Questionnaire
Timepoint

Measuring the fatigue score before the intervention and one month after the intervention

Method of measurement

Fatigue score of Cancer Fatigue Scale Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

FIRST Intervention group: In the acupressure group, in parallel with these routine cares, acupressure will be performed for each sample using the SP6 point for four weeks and every day (5 minutes) by the researcher.

Category

Prevention

2

Description

SECOND Intervention group: In the foot massage therapy group, the intervention will be such that for the patients of this intervention group, after preparing the patient and greasing the soles of the feet with sweet almond oil, which is used for cold and wetness for all temperaments, every day for four consecutive weeks Reflexology is performed for 5 minutes on the treatment points on the soles of both feet.

Category

Prevention

3

Description

Control group: No action is taken for the control group

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital in Urmia

Full name of responsible person

Amireh Hassanpour

Street address

Urmia, Resalat Boulevard, Emergency Alley

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Phone

+98 914 239 3134

Email

amirehhassanpour@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

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Street address

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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

Oroumia University of Medical Sciences

Proportion provided by this source

30

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

Oroumia University of Medical Sciences

Full name of responsible person

Amireh Hassanpour

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

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City

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Province

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Postal code

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Email
Amirehhassanpour@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Oroumia University of Medical Sciences

Full name of responsible person
Amireh Hassanpour

Position
Nurse

Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Full name of responsible person
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Email
Amirehhassanpour@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is 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
Yes - There is a plan to make this available

Title and more details about the data/document
All data is potentially shareable after de-identifying individuals

When the data will become available and for how long
The access period starts 6 months after the results are published

To whom data/document is available
Researchers working in academic and scientific institutions

Under which criteria data/document could be used
Descriptive analyzes are allowed on the submitted dat

From where data/document is obtainable
corresponding autho

What processes are involved for a request to access data/document
The request email should be sent to the corresponding author

Comments