Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

To investigate the effect of Solar plexus reflexology of sole of the foot on pain, anxiety and physiological Indicators caused by bone marrow aspiration (BMA) in patients with leukemia

Protocol summary

Study aim

In this study, the effect of reflexology of sole of the foot reflex points on pain, anxiety and physiological parameters of bone marrow aspiration in patients with leukemia was investigated.

Design

In this clinical trial study, 70 patients who admitted to the oncology hospital and have eligible inclusion in the study are randomly divided into three groups of intervention and control.

Settings and conduct

Massage intervention in the intervention group, takes place 10 minutes after bone marrow aspiration procedure by using 10 ml of olive oil for 15 minutes for each patient's foot in the reflection points of the sole of the foot (solar plexus, pituitary and spine). To measure the main outcome variables of the study, 5 minutes before and immediately before the intervention were determined and the average of these two measurements as a score before the intervention is recorded. Also, the average of the measurements immediately after the intervention and 5 minutes after the intervention is considered as the score after the intervention. Research units are selected from patients with leukemia hospitalized in Ayatollah Khansari Hospital in Arak.

Participants/Inclusion and exclusion criteria

entry conditions: 1) Leukemia 2) Age range 18 to 60 years 3) Perform bone marrow aspiration for the first time. No entry conditions: 1) Previous experience or awareness of the impact of acupressure 2) Lack of full consciousness, having mental, visual and auditory disorders 3) History of taking anti-anxiety and sedative drugs before the study

Intervention groups

Intervention groups: Intervention group: Reflexology intervention in the reflection points of the sole of the foot (solar plexus, pituitary and spine) for 15 minutes for each foot; Control group: no intervention

Main outcome variables

Respiration rate, heart rate, arterial blood oxygen saturation, blood pressure, anxiety and pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190524043687N2**
Registration date: **2021-08-29, 1400/06/07**
Registration timing: **prospective**

Last update: **2021-08-29, 1400/06/07**
Update count: **0**

Registration date

2021-08-29, 1400/06/07

Registrant information

Name

Ali Safdari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 5861 5962

Email address

asafdari.nu@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-21, 1400/06/30

Expected recruitment end date

2022-03-21, 1401/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

To investigate the effect of Solar plexus reflexology of sole of the foot on pain, anxiety and physiological Indicators caused by bone marrow aspiration (BMA) in patients with leukemia

Public title

To investigate the effect of Solar plexus reflexology of sole of the foot on pain, anxiety and physiological Indicators caused by bone marrow aspiration (BMA) in patients with leukemia

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Catching leukemia (lymphoblastic or Myeloblastic) The age range of 18 to 60 Signature of informed consent form do bone marrow aspiration for the first time Have literacy to complete the questionnaire

Exclusion criteria:

Previous experience or awareness of the impact of acupressure Lack of full consciousness, having mental, visual and auditory disorders History of taking anti-anxiety and sedative drugs one week before participating in the study (based on the contents of the file) Drug addiction Existence of an obstacle at the site of pressure (wounds, skin diseases, etc) Existence of sensory and motor disorders in the legs and minimal ability to walk on the legs (peripheral neuropathy or vascular problems in the lower extremities)

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling was done in an accessible (easy) method among all patients with leukemia (lymphoblastic or myeloblastic) who need bone marrow aspiration hospitalized in Ayatollah Khansari Hospital in Arak. Patients with equal number of members (1: 1) are randomly assigned to each of the intervention and control groups. Due to the gradual entry of samples into the research in this research, random allocation is done by a random sequence method by a table of random numbers in Excel software. To avoid the bias of random selection of individuals to study groups, it is hidden and this sequence remains hidden until the intervention. For this purpose, consecutive dark and numbered envelopes are used to enclose the sequences.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The blind groups in this study include patients, an assistant research data collector, and a statistician; In such a way that none of the patients and also the data collector was aware of the allocation of patients to the two intervention and control groups and also the data obtained from this study without informing the statistical expert about the allocation of data to each intervention and control groups, Will be analyzed. (Explanation: In this study, the person collecting information is different from the person performing the intervention).

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

No. Arak, Sardasht, Basij Square, Arak University of Medical Sciences

City

Arak

Province

Markazi

Postal code

3848176941

Approval date

2021-08-24, 1400/06/02

Ethics committee reference number

IR.ARAKMU.REC.1400.111

Health conditions studied

1

Description of health condition studied

Acute lymphoblastic leukemia

ICD-10 code

C91.0

ICD-10 code description

Acute lymphoblastic leukemia [ALL]

2

Description of health condition studied
Pain
ICD-10 code
R52
ICD-10 code description
Pain, unspecified

3

Description of health condition studied
Anxiety
ICD-10 code
F41.1
ICD-10 code description
Generalized anxiety disorder

4

Description of health condition studied
Acute myeloblastic leukemia
ICD-10 code
C92.0
ICD-10 code description
Acute myeloblastic leukemia

Primary outcomes

1

Description
Anxiety
Timepoint
Before intervention, immediately before intervention and after intervention
Method of measurement
The State-Trait Anxiety Inventory -Spielberger

2

Description
Pain
Timepoint
Before intervention, immediately before intervention and after intervention
Method of measurement
Numeric pain rating scale (NRS)

3

Description
Heart beat
Timepoint
5 minutes before the intervention, immediately before the intervention, immediately after the intervention, 5 minutes after the intervention
Method of measurement
Number of beats per minute - pulse oximeter

4

Description
Arterial blood oxygen saturation (SPO2)
Timepoint
5 minutes before the intervention, immediately before the intervention, immediately after the intervention, 5 minutes after the intervention
Method of measurement
Percentage - pulse oximeter

5

Description
Respiratory rate
Timepoint
5 minutes before the intervention, immediately before the intervention, immediately after the intervention, 5 minutes after the intervention
Method of measurement
Count per minute - count breathing by observation

6

Description
Blood pressure
Timepoint
5 minutes before the intervention, immediately before the intervention, immediately after the intervention, 5 minutes after the intervention
Method of measurement
By sphygmomanometer

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Performing massage intervention in the reflection points of the sole of the foot. For this purpose, the researcher will start the massage intervention 10 minutes after the patients enter the bed where they are hospitalized, after passing the reflexology training course and gaining the necessary skills. First, the researcher takes out his watch, ring, and jewelry and washes and warms his hands. Then, the researcher intervenes by being at the end of the patient's bed and observing a suitable position (to create better comfort, a small pillow is placed under the patient's knees).In the intervention group, to facilitate massage and better reflexology effect, 10 ml of pure olive oil with a temperature of 18-25 ° C is used. In the first step, lubricate the patient's foot for 1 minute and begin reflexology intervention. The massage of the left foot at a slow pace, with a regular rhythm and with a depth that is tolerable by the patient lasts for 15 minutes. 5 minutes is for general massage of the sole of the foot and the next 10 minutes is for the relief of pain and anxiety caused by the procedure in the reflection points of the sole of the foot (points of the solar plexus, pituitary and spine). Then the same steps are performed on the patient's right foot. In order to reduce the

likelihood of distraction in patients, the intervention will be performed in a quiet and closed environment (if possible). It should be noted that massage intervention is performed for male patients by male researcher assistance and for female patients by a female colleague.

Category

Treatment - Other

2

Description

Control group: There is no special intervention in the control group and these patients receive only routine care.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Khansari Hospital

Full name of responsible person

Ali Safdari

Street address

NO. Hospital Ayatollah khansari , End of University Avenue , arak , Central Province

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Aliraza Kamali

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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

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Ali Safdari

Position

Nursing student of Arak University of Medical Sciences

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

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Arak University of Medical Sciences

Full name of responsible person

Razieh Mokhtari

Position

Member of Arak Nursing Faculty

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for updating data

Contact
Name of organization / entity
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asafdari.nu@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
No - There is not 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
Yes - There is a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Shared data include demographic information of participants' patients, type and method of intervention, information about anxiety, pain and physiological indicators of participants before and after the intervention.
When the data will become available and for how long
Start the access period 6 months after the results are published.
To whom data/document is available
Researchers and people working in nursing as well as people working in clinical nursing
Under which criteria data/document could be used
The obtained data can be used for education, research and clinic of nursing. The applicant must be in the field of nursing. The data applicant should use the data only for education, research and clinic of nursing.
From where data/document is obtainable
Ali Safdari, Department of critical care nursing, school of nursing, Arak university of medical sciences E mail:asafdari.nu@gmail.com
What processes are involved for a request to access data/document
After confirming that the data requester is in the field of nursing, the type of request will be answered immediately via email.
Comments