Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of foot reflexology on anxiety, pain, fatigue, nausea and vomiting in patients undergoing hematopoietic stem cell transplantation admitted in Therapeutic Training Centers of Shiraz Namazi in 1399

Protocol summary

Study aim

The effect of foot reflexology on anxiety, pain, fatigue and nausea vomiting in patients undergoing hematopoietic stem cell transplantation admitted in Bone Marrow Transplantation Department of Namazi Medical Center Shiraz in 1399

Design

A randomized controlled clinical trial with parallel groups , single blind, randomized trial

Settings and conduct

The study was performed on bone marrow transplantation unit of Namazi Hospital of Shiraz University of Medical Sciences. In this study, the individual who collects the results of the study, as well as the statistician, as well as the health care providers, will be blind to the groups until the end of the study and the data analysis and reporting.

Participants/Inclusion and exclusion criteria

The main inclusion criteria for this study are patients undergoing hematopoietic stem cell transplantation and their platelet count above 50,000. One of the main conditions for excluding platelet counts is less than 50,000 and infectious vascular and foot diseases.

Intervention groups

In the intervention group, the patient lies on a bed in a quiet room. Researcher lubricates her hands with a solution of sweet almond oil. First, the patient is given a relaxing massage for 5 minutes. Reflexologist massages the patient's thumb (the pituitary gland) and the sun area to relieve sleep and relaxation. The inner and outer edges of the foot and heel are then massaged to relieve fatigue and back pain, shoulder, hands and feet. The areas of the adrenal and thyroid glands are also massaged. Finally, a relaxing massage is performed for 5 minutes. Reflective massage will be performed in total for 10 consecutive days, each leg taking between 15 and 20 minutes. Patients in the control group did not receive any massage during these 10 days and received the same routine care as the intervention group.

Main outcome variables

Anxiety; Pain; Fatigue; Nausea and Vomiting

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191021045178N1**
Registration date: **2020-04-19, 1399/01/31**
Registration timing: **prospective**

Last update: **2020-04-19, 1399/01/31**
Update count: **0**

Registration date

2020-04-19, 1399/01/31

Registrant information

Name

Nilofar Pasyar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3623 6293

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pasyarn@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-20, 1399/03/31

Expected recruitment end date

2020-12-20, 1399/09/30

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of foot reflexology on anxiety, pain, fatigue, nausea and vomiting in patients undergoing hematopoietic stem cell transplantation admitted in Therapeutic Training Centers of Shiraz Namazi in 1399

Public title
The effect of foot reflexology on patients undergoing hematopoietic stem cell transplantation

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Patients undergoing hematopoietic stem cell transplantation Male and female patients over the age of 18 years Awareness of time, place and person Serum platelet levels above 50,000 Interested in participating in the study

Exclusion criteria:
Serum platelet levels less than 50,000 Infectious or bleeding diseases and wounds in the legs Deep vein thrombosis Reflective massage intolerance patient dissatisfaction to continue participation in the study Patient's death

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Eligible patients who will undergo hematopoietic stem cell transplantation and will be admitted to the bone marrow transplantation ward of Therapeutic Training Centers of Shiraz Namazi will be recruited based on easy sampling. Then block production software will be used to randomly assign people to groups.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, the data collector, the data analyzer, and the clinical caregivers are grouped into two groups of intervention and control.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences

Street address
Vice Chancellor for Research, Seventh Floor, Shiraz University of Medical Sciences, Next to the Red Crescent, Zand Street, Shiraz, Iran

City
Shiraz

Province
Fars

Postal code
7134814336

Approval date
2020-02-15, 1398/11/26

Ethics committee reference number
IR.SUMS.REC.1398.1329

Health conditions studied

1

Description of health condition studied
Patients undergoing hematopoietic stem cell transplantation

ICD-10 code
C96.9

ICD-10 code description
Malignant neoplasm of lymphoid, hematopoietic and related tissue, unspecified

Primary outcomes

1

Description
Fatigue

Timepoint
Before intervention, 7 and 10 days after intervention

Method of measurement
Brief Fatigue Inventory

Secondary outcomes

1

Description
Anxiety

Timepoint
Before intervention, 7 and 10 days after intervention
Method of measurement
Spielberger anxiety inventory

2

Description
Pain
Timepoint
Before intervention, 7 and 10 days after intervention
Method of measurement
Numeric Pain Scale

3

Description
Nausea and vomiting
Timepoint
Before intervention, 7 and 10 days after intervention
Method of measurement
Rhodes inventory (Index of Nausea, Vomiting and Retching)

Intervention groups

1

Description
Intervention group: In the intervention group, the patient lies on a bed in a quiet room. The researcher sits at the bottom of the patient's bed and rubs his hands with sweet almond oil solution, which has no treatment, to massage the data to create proper heat in the hands, while performing a slippery massage. The procedure for massaging the legs is to start from the right foot to the left. The way to do this massage is to first massage the patient for 5 minutes by applying vibration, rotation and stretching techniques. The reflexologist then presses with the thumb on the patient's thumb (the pituitary area) and the solar region, which is related to sleep and relaxation. Then massage the inner and outer edges of the soles of the foot and then massage the heel to relieve fatigue and back pain, shoulders, hands and feet. The areas of the adrenal and thyroid glands are also massaged. Lastly, massage for 5 minutes. Reflective massage will generally be performed in 10 consecutive days, each session lasting 30 to 40 minutes (each leg approximately 15 to 20 minutes).
Category
Rehabilitation

2

Description
Control group: The control group did not receive any massage. This group, similar to the intervention group, received routine care.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Namaz Hospital of Shiraz
Full name of responsible person
Niloofar Pasyar
Street address
School of Nursing and Midwifery, Namazi Square, Zand Street, Shiraz, Iran
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7193613119
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Younes Ghasemi
Street address
Deputy of Research and Technology, 7th Floor, Central Building of Shiraz University of Medical Sciences, Zand Street
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+98 71 3212 2430
Email
vcrdep@sums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Niloofar Pasyar

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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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

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

The main consequence

When the data will become available and for how long

6 months after the publication of the article

To whom data/document is available

Academic institutions

Under which criteria data/document could be used

Data can only be approved by the journal before the article is published and no other use is permitted.

From where data/document is obtainable

Contact pasyarn@yahoo.com for information.

What processes are involved for a request to access data/document

Contact pasyarn@yahoo.com for information.

Comments