Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of the Slow Stroke Back Massage on the pain and fatigue severity in the patients with acute leukemia undergoing chemotherapy.

Protocol summary

Summary

The purpose of this study was to determine the effects of slow stroke back massage on pain severity and fatigue level of patients receiving chemotherapy for acute leukemia. This study was a blind prospective clinical trial with random assignment. Inclusion criteria included being 18-50 years old, pain and fatigue severity 3 or more (on the basis of numeric rating scale) before intervention, the patients should have been under chemotherapy and exclusion criteria included absence in two sessions of massage therapy, discharge or death of the patient, and the patient's unwillingness to continue to participate in the study. 60 patients with acute leukemia were treated with slow stroke back massage for one month (three 10-minute sessions per week) and then pain severity and fatigue level of them were measured.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015030221307N1**
Registration date: **2015-05-13, 1394/02/23**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-05-13, 1394/02/23

Registrant information

Name

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Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2015-04-19, 1394/01/30

Expected recruitment end date

2015-05-10, 1394/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of the Slow Stroke Back Massage on the pain and fatigue severity in the patients with acute leukemia undergoing chemotherapy.

Public title

Effect of the massage therapy on the patients with acute blood cancer

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: ages ranging from 18 to 50 years; pain and fatigue severity 3 or more (on the basis of numeric rating scale); no sign of clear and identified pain or fatigue disorders which are recorded in patients' files (pains from lumbar disc, spinal injuries, fractures, etc. and fatigue from Thalassemia, Sickle cell anemia, etc.); not having any background diseases (such as diabetes, peripheral nerves disease); the patients should have been under chemotherapy. Exclusion criteria: absence in two sessions of massage therapy; discharge or death of

the patient; and the patient's unwillingness to continue to participate in the study.

Age
From **18 years** old to **50 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size:

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Matching on the basis of age and gender. Random allocation, the first three patients assigning to the intervention group and the second three patients to the control

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ahvaz Jundishapur University of Medical Science

Street address
Research center, Golestan Blv

City
Ahvaz

Postal code

Approval date
2015-02-21, 1393/12/02

Ethics committee reference number
Ajums.rec.1393.388

Health conditions studied

1

Description of health condition studied
Acute leukemia

ICD-10 code
C91.0, C92

ICD-10 code description
Acute lymphoblastic leukaemia [ALL], Acute myeloblastic leukaemia [AML]

Primary outcomes

1

Description
Pain severity

Timepoint
Before intervention, at the end of each week, after intervention

Method of measurement
Numeric rating scale (NRS)

2

Description
Fatigue severity

Timepoint
Before intervention, at the end of each week, after intervention

Method of measurement
Numeric rating scale (NRS)

Secondary outcomes

1

Description
nausea severity

Timepoint
Before intervention, at the end of each week, after intervention

Method of measurement
Numeric rating scale (NRS)

2

Description
Quality of life

Timepoint
Before and after of intervention

Method of measurement
Short-Form 36 Health Survey (SF-36)

3

Description
Sleep quality

Timepoint
Before and after of intervention

Method of measurement
Pittsburgh Sleep Quality Index (PSQI)

4

Description
Mood disturbances

Timepoint
Before and after of intervention

Method of measurement
Beck Depression questionnaire and Spielberg Anxiety questionnaire

5

Description
Sleep disturbance severity
Timepoint
Before intervention, at the end of each week, after intervention
Method of measurement
Numeric rating scale (NRS)

Intervention groups

1

Description
Both groups will receive the routine cares. The intervention group will be treated with slow stroke back massage. 1- The patient sits on a chair and leaned his head on the pillow, 2 - The small rotational movements with the thumb on the neck, 3- To stroke surface the base of the skull to the sacrum with the palm of a hand, and repeat the procedure on the other side of the spine with the other hand, While at it, the first hand moves toward the base of the skull, 4 – To do stoke on shoulder blades with thumb. 5 - Stroke with the thumb on either side of the spine from the shoulders to the waist, 6 - Stroke to sweep the neck to the sacrum with the palms of both hands.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Ahvaz Shfa Hospital
Full name of responsible person
Dr Ahmadzadeh
Street address
Ahvaz Shfa Hospital, University Of Medical Science, Golestan Blv, Ahvaz, Iran
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Ahvaz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz Jundishapur University of Medical Science
Full name of responsible person
Mr Kouresh Zareia
Street address
Research center, University of Medical Science, Golestan Blv, Ahvaz, Iran
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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
Ahvaz Jundishapur University of Medical Science
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

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Ahvaz Jundishapur University of Medical Sciences
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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