

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 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

Mojtaba Miladinia

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

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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 stroke 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

City

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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Ahvaz

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

Contact

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

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Position

Assistant Professor

Other areas of specialty/work

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Other areas of specialty/work

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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