

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Effect of acupressure on fatigue and anxiety in the patients with cancer: single-blind randomized clinical trial in three groups (intervention, placebo and control)

Protocol summary

Summary

Objective: effect of acupressure on fatigue and anxiety in the patients with cancer. Design: a single-blind randomized clinical trial. Setting and conduct: the patients with cancer in hematology unit will be included in the study with the following criteria: (a) II, III, and IV stages of cancer; (b) consciousness; (c) lack of amputation or ulcer at acupoints; (d) lack of severe heart failure; (e) lack of hypothyroidism; (f) lack of coagulant disorders. The patients will be excluded from the study with the following criteria: (a) hemoglobin less than nine gram per deciliter; (b) platelet less than 50000 per microliter; (c) pregnancy. Intervention: in the intervention group acupressure will be conducted on the fifteen correct acupoints in the ten sessions for half an hour during two weeks. In the placebo group acupressure will be conducted on the fifteen sham acupoints close to correct acupoints in the ten sessions for half an hour during two weeks. In the control group the patients will be received only routine cares. Main outcome measures: fatigue and anxiety will be assessed with questionnaires as following: (a) fatigue will be assessed with the Brief Fatigue Inventory questionnaire before intervention, before the sixth session of intervention and after the tenth session of intervention; (b) anxiety will be assessed with the Spielberger anxiety questionnaire before the intervention, before the sixth session of intervention and after the tenth session of intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201301219759N2**

Registration date: **2013-02-12, 1391/11/24**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-02-12, 1391/11/24

Registrant information

Name

Ali Bikmoradi

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 81 1838 0439

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Recruitment status

Recruitment complete

Funding source

Vice-Chancellor of Research and Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2013-02-08, 1391/11/20

Expected recruitment end date

2013-05-10, 1392/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of acupressure on fatigue and anxiety in the patients with cancer: single-blind randomized clinical trial in three groups (intervention, placebo and control)

Public title

Effect of acupressure on fatigue and anxiety in the patients with cancer

Purpose
Supportive

Inclusion/Exclusion criteria
The patients with cancer in hematology unit will be included in the study with following criteria: (a) II, III, and IV stages of cancer; (b) consciousness; (c) lack of amputation or ulcer at the acupoints; (d) lack of severe heart failure; (e) lack of hypothyroidism; (f) lack of coagulant disorders. The patients will be excluded from the study with the following criteria: (a) hemoglobin less than nine gram per deciliter; (b) platelet less than 50000 per microliter; (c) pregnancy.

Age
From **18 years** old to **64 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
In this study, the balanced block randomization will be used and the patients allocated in three groups; intervention group (acupressure on the correct acupoints), placebo group (acupressure on the sham acupoints) and control group (routine cares). Acupressure will be conducted (as single-blind) on the correct and sham acupoints in two groups of intervention and placebo. So the patients will be not informed about the kind of acupressure.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Human Subject Review Board of Hamadan
University of Medical Sciences

Street address

Hamadan University of Medical Sciences, Shaheed
Fahmideh Ave.

City

Hamadan

Postal code

6517838698

Approval date

2013-01-01, 1391/10/12

Ethics committee reference number

D/P/16/35/9/3496

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F41.3

ICD-10 code description

Other mixed anxiety disorders

2

Description of health condition studied

Cancer

ICD-10 code

C00, C01,

ICD-10 code description

Malignant neoplasms, stated or presumed to be primary, of specified sites, except of lymphoid, haematopoietic and related tissue

3

Description of health condition studied

Cancer

ICD-10 code

C76, C77,

ICD-10 code description

Malignant neoplasms of ill-defined, secondary and unspecified sites

4

Description of health condition studied

Cancer

ICD-10 code

C97

ICD-10 code description

Malignant neoplasms of independent (primary) multiple sites

5

Description of health condition studied

Cancer

ICD-10 code

D00, D01,

ICD-10 code description

In situ neoplasms

6

Description of health condition studied

Cancer

ICD-10 code

D37, D38,
ICD-10 code description
Neoplasms of uncertain or unknown behaviour

7

Description of health condition studied

Fatigue

ICD-10 code

R53

ICD-10 code description

Malaise and fatigue

8

Description of health condition studied

Cancer

ICD-10 code

C81, C82,

ICD-10 code description

Malignant neoplasms, stated or presumed to be primary, of lymphoid, haematopoietic and related tissue

Primary outcomes

1

Description

Fatigue

Timepoint

Before intervention, before the sixth session of intervention and after the tenth session of intervention

Method of measurement

Brief Fatigue Inventory questionnaire

2

Description

Anxiety

Timepoint

Before intervention, before the sixth session of intervention and after the tenth session of intervention

Method of measurement

Spielberger anxiety questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: in the intervention group acupuncture will be conducted on the fifteen correct acupoints in ten sessions for half an hour during two weeks.

Category

Treatment - Other

2

Description

Placebo group: in the placebo group acupuncture will be conducted on the fifteen sham acupoints close to correct acupoints in the ten sessions for half an hour during two weeks.

Category

Treatment - Other

3

Description

Control group: in the control group the patients will be received only routine cares.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Therapeutic and Educational Center of Hamadan

Full name of responsible person

Fatemeh Najafi

Street address

Nursing and Midwifery School, Hamadan University of Medical Sciences, Shaheed Fahmideh Ave.

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-Chancellor of Research and Technology, Hamadan University of Medical Sciences

Full name of responsible person

Dr. Ahmad Tavalani

Street address

Vice-Chancellor of Research and Technology, Hamadan University of Medical Sciences, Shaheed Fahmideh Ave.

City

Hamadan

Grant name

از محل یک درصد بودجه طرح های تحقیقاتی دانشگاه

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice-Chancellor of Research and Technology, Hamadan University of Medical Sciences

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
Department of Medical Surgical Nursing
Full name of responsible person
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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