Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of Shiatsu massage on physiological parameters ,anxiety and pain during chemotherapy in patients with breast cancer

Protocol summary

Study aim
Evaluation of the effectiveness of Shiatsu massage on physiological index, anxiety and pain during chemotherapy in patients with breast cancer

Design
Clinical trial with control group, with parallel groups, Single blinded, randomized

Settings and conduct
In this study, 72 patients with breast cancer undergoing chemotherapy hospitalized in Ayatollah Khansari hospital in Arak city were selected and with random blocks will be divided to two groups of experimental and control. Alternate shiatsu will be performed for 5 minutes massage and 2-minute rest to 20 minutes by the intervention group, control group during this period will receive touch without pressure for 20 minutes.

Participants/Inclusion and exclusion criteria
Inclusion criteria:Cancer patients who have undergone at least one course of chemotherapy; age more than 18 and under 60, diagnosed with stage 2, 3, and 4 cancers at the discretion of the relevant physician; cancer patients with 6 months from the date of diagnosis exclusion criteria: Any life-threatening emergency situation ;skin diseases such as ulcers and infections of hand

Intervention groups
For the intervention group, during chemotherapy, a one-time Shiatso massage will be performed on the Hugo spots for 5 minutes and 2 minutes of rest for up to 20 minutes. In the control group during chemotherapy, patients do not receive any intervention from the researcher for Shiatsu massage. In this group, only a touch without pressure will be performed for 20 minutes. The amount of pain, anxiety and physiological signs will be measured before and immediately after the intervention by tools and questionnaires.

Main outcome variables
Anxiety rate; Pain rate; Number of breaths;Blood pressure; Heart rate

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20151002024290N2**
Registration date: **2020-05-25, 1399/03/05**
Registration timing: **prospective**

Last update: **2020-05-25, 1399/03/05**
Update count: **0**

Registration date
2020-05-25, 1399/03/05

Registrant information

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Zohreh Farahani

Name of organization / entity
Arak Medical University

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-06-21, 1399/04/01

Expected recruitment end date
2020-09-22, 1399/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of Shiatsu massage on physiological parameters ,anxiety and pain during chemotherapy in patients with breast cancer

Public title
The effect of Shiatsu massage in patients with breast cancer under chemotherapy
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Cancer patients who have been undergoing chemotherapy for at least one period. Age more than 18 and less than 60 years. Diagnosis of stages 2, 3 and 4 of cancer According to the relevant physician. Cancer patients with 6 months of diagnosis Full of consciousness No history of mental illness, seizures or epilepsy, asthma, thyroid disorder, olfactory disorder, severe heart failure that has been approved by a doctor No history of smoking and drug addiction Under chemotherapy with a special protocol
Exclusion criteria:
Paralysis of the hands
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Care provider

Sample size
Target sample size: **72**
Randomization (investigator's opinion)
Randomized
Randomization description
After selecting the samples by random sampling method, they will be randomly and according to the table of random numbers in the two groups of test and control. In order to randomize the selection of 72 patients into two intervention and control groups, first 9 different blocks of 8 letters T and C are created, which indicate the intervention and control groups (4 people belonging to the intervention group and 4 people). Belong to the control group. These blocks are then randomly selected by drawing lots to obtain a 72-bit combination of blocks, respectively. The resulting combination of letters is placed one by one in 72 closed envelopes, respectively, and with the visit of each patient, one envelope is opened in order to determine in which group the patient is placed.
Blinding (investigator's opinion)
Single blinded
Blinding description
It should be noted that the nurse who will measure vital signs and the level of anxiety and pain of the patient through the Spielberger questionnaire tool and the visual scale of pain will be unaware of the type of intervention being performed
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 sciencese
Street address
Arak, Basij Square, Campus University of Medical Sciences Campus, School of Nursing
City
Arak
Province
Markazi
Postal code
3848176341
Approval date
2019-08-06, 1398/05/15
Ethics committee reference number
IR.ARAKMU.REC.1398.091

Health conditions studied

1

Description of health condition studied
Breast Cancer
ICD-10 code
C50
ICD-10 code description
Malignant neoplasm of breast

Primary outcomes

1

Description
Anxiety
Timepoint
Measure the amount of anxiety before each chemotherapy treatment with the intervention and immediately after each chemotherapy treatment with the intervention.
Method of measurement
Spielberger Questionnaire

2

Description
Pain
Timepoint
Measure the amount of pain before each chemotherapy

treatment with the intervention and immediately after each chemotherapy treatment with the intervention.

Method of measurement

Visual analog scale

3

Description

Blood pressure

Timepoint

Measure the amount of blood pressure before each chemotherapy treatment with the intervention and immediately after each chemotherapy treatment with the intervention

Method of measurement

Mercury blood pressure device

4

Description

Number of heartbeats

Timepoint

Measure the amount of number of heartbeats before each chemotherapy treatment with the intervention and immediately after each chemotherapy treatment with the intervention

Method of measurement

Cardiac and pulmonary monitor device

5

Description

Number of breaths

Timepoint

Measure the amount of number of breaths before each chemotherapy treatment with the intervention and immediately after each chemotherapy treatment with the intervention

Method of measurement

Cardiac and pulmonary monitor device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:For the intervention group, during chemotherapy, a one-time Shiatso massage will be performed on the Hugo spots for 5 minutes and 2 minutes of rest for up to 20 minutes. The amount of pain, anxiety and physiological signs will be measured before and immediately after the intervention by tools and questionnaires.

Category

N/A

2

Description

Control group: Patients in the control group do not receive any Shiatsu massage intervention on the part of the researcher. In this group, only touch without pressure will be done for 20 minutes.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Khansari Hospital

Full name of responsible person

Zohreh Farahani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Alireza 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
Zohreh Farahani
Position
Academic Instructor Faculty Of Nursing
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Master
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available