Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The influence of massage therapy on depression, anxiety and severity of nausea and vomiting in patient with breast cancer undergoing chemotherapy

Protocol summary

Summary
This study evaluates the effects of massage therapy on anxiety, depression, nausea and vomiting in patients with breast cancer undergoing chemotherapy. Subjects and Methods: This study was a clinical trial of 34 patients with breast cancer chemotherapy regimen TAC. After initial assessment of patients to make sure that they have some degree of depression and anxiety and have had nausea and vomiting during previous chemotherapy, patients randomly divided into intervention and control groups. Intervention group had three sessions of Stroke and Kneading back massage in addition to the usual care they received. Control group only received their usual care. Baseline information was gathered on the first day for both groups. 24 hours after each massage the following questionnaires were filled for the patients: the Beck Depression Inventory, Anxiety Spill Burger questionnaire, VAS (Visual Analogue Scale) and a form to record the number of vomitings were completed. Keywords: breast cancer, massage, anxiety, depression, nausea, vomiting, chemotherapy

General information

Acronym

IRCT registration information
IRCT registration number: **IRCT138903244138N2**
Registration date: **2010-10-06, 1389/07/14**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date
2010-10-06, 1389/07/14

Registrant information
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Somaieh Bosak
Name of organization / entity
medical sceince university
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Recruitment status
Recruitment complete

Funding source
pro vice chancellor for research

Expected recruitment start date
2009-12-14, 1388/09/23
Expected recruitment end date
2010-05-05, 1389/02/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The influence of massage therapy on depression, anxiety and severity of nausea and vomiting in patient with breast cancer undergoing chemotherapy

Public title
The influence of massage therapy on depression, anxiety and severity of nausea and vomiting in patient with breast cancer undergoing chemotherapy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria 1 - All patients received at least one cycle of chemotherapy. 2 – had some degree of anxiety

and depression. 3 -complaining from nausea and vomiting after chemotherapy. 4. All the patients to receive ACTAXOL regimen. 5. be fluent in Farsi. Exclusion criteria 1 - any disease or condition that cause nausea and vomiting, such as intestinal obstruction, metastasis to the gastrointestinal tract and central nervous system, etc. 2 - Patients with chronic history of mental problems (such as chronic depression and anxiety, and use of antipsychotics). 3 -Patients who are using psychiatric drugs. 4 - use of chemotherapy with radiotherapy. 5 - use of other methods of alternative medicine or herbal treatments to control nausea and vomiting, depression and anxiety during the study. 6 - Ill patients that are unable to answer questions. 7. Any tumors, ulcers, burns, skin lesion in the lumbar area that may interfere with proper conduction of the massage

Age
No age limit
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **34**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Jondishapour medical university of Ahwaz
Street address
Central department, Ahwaz university of medical sciences, Golestan
City
Ahwaz
Postal code
Approval date
empty
Ethics committee reference number
8/20/484/پ

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
24 hour
Method of measurement
Spillburger Anxiety questionnaire

2

Description
depression
Timepoint
24 hour
Method of measurement
Beck depression questionnaire

Secondary outcomes

1

Description
nausea
Timepoint
24 hour
Method of measurement
VAS questionnaire

2

Description
vomitting
Timepoint
24 hour
Method of measurement
form of number of vomitting

Intervention groups

1

Description
Control group: Standard care including antiemetic regimen Ketryl and Dexamethasone
Category
Treatment - Drugs

2

Description
Intervention group: standard care including antiemetic regimen Ketryl and Dexamethasone in addition to 3 sessions of Stroke and Kneading back massage each lasting 20 minute
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
center of oncology and radiation therapy of Golestan hospital
Full name of responsible person
Bahman Dashtbozorgi, Ahwaz University of Medical Sciences
Street address
Central library of
City
Ahwaz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahwaz university of medicine
Full name of responsible person
Pro vice chancellor for research
Street address
Ahwaz University of Medical Sciences, Golestn
City
Ahwaz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahwaz university of medicine
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
Ahwaz University of Medical Sciences
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Position
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Web page address

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