

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Comparison of the effect of abdominal massage with and without *Salvia officinalis* aromatic substance on nausea, vomiting, and constipation of patients undergoing chemotherapy

Protocol summary

Study aim

Comparison of the effect of abdominal massage with and without *Salvia officinalis* aromatic substance on nausea, vomiting, and constipation of patients undergoing chemotherapy

Design

In this study samples will select by convenience sampling method .Then randomly will be allocated blocks into three groups;2 intervention groups (25 massage with *salvia officinalis*, 25 non-aromatic massage) and 25 in the control group .Nausea, vomiting and constipation in three groups will be measured before and after the study.

Settings and conduct

The abdominal Swedish way massage with or without scented *salvia officinalis* twice a day in oncology wards.

Participants/Inclusion and exclusion criteria

- Age over 18 years
- Constipation Assessment score of eight or higher
- Absence of coagulation disorder
- No history of migraine and chronic headache
- No history of allergy to herbs
- Lack of Meniere's syndrome
- Having no respiratory problems
- Insensitivity to aromatic substances
- no history of respiratory disease such as asthma, rhinitis, sinus disorders
- Do not use aromatherapy for patients within one week prior to the intervention

Intervention groups

For the control group, do not take any intervention. In massage group without aromatic substances, only massage without abdominal matter will be used. In group with aromatic matter; abdominal massage with *salvia officinalis* will be used. How to do an intervention in a massage group with a scented substance is exactly the same as a massaging group without aromatic matter, with the difference that in this method of use the aromatic herbal syrup of 2 cc (making barij Kashan essential oil) at each massage time for abdominal

massage will be.

Main outcome variables

Nausea, vomiting and constipation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141109019862N7**

Registration date: **2019-04-20, 1398/01/31**

Registration timing: **prospective**

Last update: **2019-04-20, 1398/01/31**

Update count: **0**

Registration date

2019-04-20, 1398/01/31

Registrant information

Name

Sakine Sabzevari

Name of organization / entity

Kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-21, 1398/02/01

Expected recruitment end date

2019-10-23, 1398/08/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of abdominal massage with and without Salvia officinalis aromatic substance on nausea, vomiting, and constipation of patients undergoing chemotherapy

Public title
Comparison of the effect of abdominal massage with and without Salvia officinalis aromatic substance on nausea, vomiting, and constipation of patients undergoing chemotherapy

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Age over 18 years Constipation Assessment Score of eight or higher
Exclusion criteria:
 Coagulation disorders History of migraine and chronic headache History of allergy to herbs Meniere's syndrome Respiratory problems Sensitivity to aromatic substances History of respiratory disease such as asthma, rhinitis, sinus disorders Use aromatherapy for patients one week before intervention

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **75**

Randomization (investigator's opinion)
Randomized

Randomization description
Samples (75 people) will select by convenience sampling method .Then randomly will be allocated blocks into three groups;2 intervention groups (25 massage with salvia officinalis , 25 non-aromatic massage) and 25 in the control group. In this method, random block allocation will perform by the software.

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

Ethical committee of Kerman University of Medical Sciences

Street address

Jahad Blvd, Ebn Sina avenue

City

kerman

Province

Kerman

Postal code

76177

Approval date

2019-02-18, 1397/11/29

Ethics committee reference number

IR.KMU.REC.1397.464

Health conditions studied

1

Description of health condition studied

neoplasm

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Nausea, vomiting and constipation

Timepoint

Before intervention, immediately after abdominal massage, and a week after abdominal massage.

Method of measurement

The instrument will be a questionnaire consisting of three parts; demographic information, Constipation Assessment Scale and Visual Analog Scale for nausea and vomiting.

Secondary outcomes

empty

Intervention groups

1

Description

Control group: In this group for the control of nausea, vomiting and constipation are the drugs prescribed by the doctor digestive and laxative use and there is no intervention.

Category

N/A

2

Description

Intervention group: In this group, in addition to routine care only of abdominal massage without aromatic material will be used. Before the massage, patient privacy is maintained. How do massage is the massage for half an hour on an empty stomach before feeding is done for patient comfort. The patient is placed in the back rest so that the legs bend from the knees slightly and the head is at an angle of 15 to 30 degrees. Coverage of the massage area is removed from the upper anterior lobe of the iliac buccal underneath the lower chest ribs and the rest of the body is covered. Then the massage therapist, who is a member of the patient family, is on the right and facing the lower level of the patient's pelvis. Massage begins. It should be noted that accompanying the patient after examination of the patient's stomach in terms of mass and other prohibitions of massage, in the absence of a problem, massage begins. Massage in a clockwise direction and start from scratch ascending colon, the colon and the descending colon landscape and finally to the end of the massage continues. Massage in Swedish massage style involves stroking or stroking, eyelinating, or gyrotic, vibration or vibration and hand massage or nidding 2 times a day for 15 minutes at 8:30 and 20:30. Massage time is set to take place at fixed intervals and not interfere with the patient's sleep.

Category

Other

3

Description

2 Intervention group: In this group, in addition to routine care abdominal massage with salvia officinalis will be used. How to do an intervention in a massage group with a scented substance is exactly the same as a massaging group without aromatic matter, with the difference that in this method of use 2 cc the salvia officinalis (making barij Kashan essential oil) at each massage time for abdominal massage will be.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

All centers of oncology (Beysat Specialist Clinic, Samen Alaeman Clinic, Jawat Alaem Specialist Clin

Full name of responsible person

Dr Sakineh Sabzevari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

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Grant name

No Funding

Grant code / Reference number

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

Yes

Title of funding source

Kerman University of Medical Sciences

Proportion provided by this source

1

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

Kerman University of Medical Sciences

Full name of responsible person

Dr Sakineh Sabzevari

Position

Associate Professor, Faculty Member

Latest degree

Ph.D.

Other areas of specialty/work

Medical Education

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

As an original article

When the data will become available and for how long

After publish as an article in a journal

To whom data/document is available

Public

Under which criteria data/document could be used

For undergoing chemotherapy patients and research fields

From where data/document is obtainable

Published documents

What processes are involved for a request to access data/document

Via email

Comments