

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

The effect of aromatherapy with Citrus aurantium essential oil and foot reflexology on relieve pain in patients with cancer undergoing chemotherapy in hospital

Protocol summary

Study aim

Determining the effect of aromatherapy with spring orange essential oil and plantar reflexology on pain relief in cancer patients undergoing chemotherapy in hospital

Design

Clinical trial with control group, with parallel groups, Double blind, randomized, on 160 randomized patients

Settings and conduct

On cancer patients admitted to Qazvin provincial hospital who are undergoing chemotherapy. Participants and treatment staff will not know about the study group.

Participants/Inclusion and exclusion criteria

Inclusion criteria include having at least 18 years of age, that the person is able to understand Persian and speak Persian and willing to participate in the study, having a pain score of at least 3 based on the VAS scale before the intervention, having alertness and awareness To the place and time, not having any allergies to odor, olfactory disorders, any plague, paresthesia and infectious or bleeding wounds in the legs are other criteria for inclusion in the study.

Intervention groups

The samples will be divided into four groups including three experimental groups and one control group. In the first experimental group, aromatherapy with spring orange will be performed in the second experimental group for half an hour according to the reflexology pain points of the sole of the foot. In the third test group, foot reflexology and aromatherapy with spring orange essential oil will be performed simultaneously on the samples. In the control group, the samples will not receive any type of massage, reflexology or fragrance. It should be noted that all four groups will receive routine hospital care.

Main outcome variables

Pain score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210412050939N1**

Registration date: **2021-06-01, 1400/03/11**

Registration timing: **registered_while_recruiting**

Last update: **2021-06-01, 1400/03/11**

Update count: **0**

Registration date

2021-06-01, 1400/03/11

Registrant information

Name

Farhad Inanloo tayefeh yaghmorloo

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3355 8245

Email address

farhad.inanloo@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-21, 1400/02/01

Expected recruitment end date

2021-07-23, 1400/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of aromatherapy with Citrus aurantium essential oil and foot reflexology on relieve pain in patients with cancer undergoing chemotherapy in hospital

Public title

The effect of aromatherapy with Citrus aurantium essential oil and foot reflexology on relieve cancer pain

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Be at least 18 years old
The person is able to understand Persian and speak Persian and is willing to participate in the study
Have a pain score of at least 3 based on the VAS scale before the intervention
Platelets above 50,000 in Reflexology groups
Positive olfactory test in aromatherapy groups
Negative sensitivity testing in aromatherapy groups

Exclusion criteria:

Lack of knowledge of time, place and person
Lack of full consciousness
Existence of known mental disorders
Having Deep vein thrombosis
Having coagulation disorders
Acute skin problems and infections and skin lesions
Existence of open wounds in the legs
Existence of recent burns
Existence of fractures
Extensive bruises on the legs

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **160**

Randomization (investigator's opinion)

Randomized

Randomization description

Random randomization will be done by web randomization method and using the website <https://www.sealedenvelope.com/>. The assignment sequence will be determined by first assigning the letters A, B, C, and D to each of the study groups. The size of the blocks will be eight (twice the number of groups), but the size of the blocks is not said by the researcher so that the person doing the sampling is not aware of it and can not predict how to allocate and in Prevent selection error. After listing almost all possible modes, six blocks, and assigning a number to each of them using a random number table, a number of blocks will be selected to increase the sample size to 160.

Blinding (investigator's opinion)

Double blinded

Blinding description

To blind the researcher, the pain assessment of the

samples before and after the intervention is done by an assistant researcher who will also be unaware of the allocation of study groups. Also, the analyzer will not know about the study groups and will analyze the data only with the codes that are considered for each group.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Zanjan University of Medical Sciences

Street address

Zanjan University of Medical Sciences

City

Zanjan

Province

Zanjan

Postal code

4513956184

Approval date

2021-04-11, 1400/01/22

Ethics committee reference number

IR.ZUMS.REC.1400.023

Health conditions studied**1****Description of health condition studied**

Cancer

ICD-10 code

Z92.21

ICD-10 code description

Personal history of antineoplastic chemotherapy

Primary outcomes**1****Description**

Pain score on the VAS scale

Timepoint

Measure the pain score before and one hour after the intervention

Method of measurement

VAS scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the first experimental group, aromatherapy with spring orange in such a way that with a dropper of three drops of 10% essential oil of spring orange, Barich essential oil is poured on the gas and placed in a box 30 cm away from the patient's head. From the intervention and one hour after the intervention, it will be completed for three days (that is, 3 times before the intervention and 3 times after the intervention, the pain assessment sheet will be completed). In order to prevent the possible occurrence of allergy to spring orange essential oil in other patients who are present in the ward but are not included in this study, we will try to study in more secluded rooms with a maximum of two beds, as well as for other patients in the room. There are also tests for sensitivity to essential oils, will be performed by the said method.

Category

Other

2

Description

Intervention group: In the second test group, reflexology of the sole of the foot will be performed for half an hour according to the pain points. During this study, each night before the intervention and one hour after the intervention for three nights, the subjects were asked to complete the pain measurement tool.

Category

Other

3

Description

Intervention group: In the third experimental group, plantar reflexology and aromatherapy with spring orange essential oil simultaneously

Category

Other

4

Description

Control group: In the control group, the samples will not receive any kind of massage, reflexology or fragrance and will receive only the usual care of the ward.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Velayat hospital

Full name of responsible person

Dr Maryam Rajabi

Street address

Velayat Hospital, Taavon Square, 22 Bahman Blvd, Elahieh Alley, Minoodar.

City

Qazvin

Province

Qazvin

Postal code

0000000000

Phone

+98 28 3379 0620

Email

farhad.inanloo@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Dr Maziar peyda

Street address

Zanjan University of Medical Sciences, Zanjan

City

Zanjan

Province

Zanjan

Postal code

4513956184

Phone

+98 24 3315 6142

Email

mazyarpeyda@zums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zanjan 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

Zanjan University of Medical Sciences

Full name of responsible person

Masoomah Mortagha Ghasemi

Position

Faculty instructor

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Zanjan University of Medical Sciences

City

Zanjan

Province

Zanjan

Postal code

4513956184

Phone

+98 24 3314 8263

Fax**Email**

mmortaghyghasemy@yahoo.com

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

No 58, behzadpour Alley, Rah ahan Ave

City

Qazvin

Province

Qazvin

Postal code

3417747649

Phone

+98 28 3355 8245

Fax**Email**

Farhad.inanloo@zums.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Zanjan University of Medical Sciences

Full name of responsible person

Masoomeh Mortagha Ghasemi

Position

Faculty instructor

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Zanjan University of Medical Sciences

City

Zanjan

Province

Zanjan

Postal code

4513956184

Phone

+98 24 3314 8263

Fax**Email**

mmortaghyghasemy@yahoo.com

Person responsible for updating data**Contact****Name of organization / entity**

Zanjan University of Medical Sciences

Full name of responsible person

Farhad Inanloo tayefeh yaghmorloo

Position

Nurse

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

Yes - There is a plan to make this available

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

Yes - There is a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

All data is potentially shareable after unidentified individuals.

When the data will become available and for how long

Access period starts from 2021

To whom data/document is available

The data will be available to researchers from academic and scientific institutions.

Under which criteria data/document could be used

Researchers will only be allowed access to advance academic research goals.

From where data/document is obtainable

It will be possible to receive documents in the dissertation bank of the Central Library of Zanjan University of Medical Sciences.

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

It will be possible to receive documents in the dissertation bank of the Central Library of Zanjan University of Medical Sciences.

Comments