

# 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

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#### 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

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##### Province

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##### Postal code

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##### 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

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**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**

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**Other areas of specialty/work**

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**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**