Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

Investigation the effect of oral Rosemary hydro-alchohlic extract on chemotherapy induced peripheral neuropathy in the patients with metastatic gastrointestinal malignancy: A randomized clinical trial

Protocol summary

Study aim

Determining the effect of oral Rosemary hydro-alcoholic extract on chemotherapy induced peripheral neuropathy in patients with metastatic gastrointestinal cancer

Design

This study is a double-blind randomized controlled clinical trial in which 52 patients are randomly assigned to one of two intervention and control (placebo) groups. In order to equalize the distribution of the important confounders of gender, age and type of cancer, classes based on these variables are classified, and then they are placed in 2 study groups in a balanced way by block randomization.

Settings and conduct

Patients referring Shahid Rahimi Hospital for chemotherapy are included in the study after giving written informed consent. Considering that the contents of the capsules are known only to the main researcher and other people are unaware of its contents. Therefore, both investigators, patients, medical staffs and data analysts are blinded in this study.

Participants/Inclusion and exclusion criteria

Patients with metastatic gastrointestinal cancer, age over 25 years, consent to participate in the study and receive chemotherapy containing oxaliplatin Non-entry Criteria: patients with significant kidney and liver function impairment

Intervention groups

In this study, patients will be randomly assigned to one of two intervention or control groups. In the intervention group, patients are given 500 mg capsules containing rosemary extract and the patient is asked to consume three capsules a day for two months. In the control group, placebo will be given.

Main outcome variables

The main outcomes including degree of peripheral neuropathy, intensity of neuropathic pain, tendon reflex, feeling of tremors, murmuring, numbness, quality of life, sensory-motor function of the patient and cognitive impairment.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200331046902N1**
Registration date: **2023-02-07, 1401/11/18**
Registration timing: **registered_while_recruiting**

Last update: **2023-02-07, 1401/11/18**
Update count: **0**

Registration date

2023-02-07, 1401/11/18

Registrant information

Name

Shahram Ahmadi Somaghian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 66 3331 4711

Email address

shahrama20@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-05, 1401/11/16

Expected recruitment end date

2023-08-23, 1402/06/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigation the effect of oral Rosemary hydro-alchohlic extract on chemotherapy induced peripheral neuropathy in the patients with metastatic gastrointestinal malignancy: A randomized clinical trial

Public title
Investigation the effect of oral Rosemary extract on chemotherapy induced peripheral neuropathy
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with metastatic gastrointestinal cancers aged 25 to 80 years undergoing chemotherapy with oxaliplatin-containing chemotherapy regimens.
Exclusion criteria:
Patients who have previously received a chemotherapy regimen containing neurotoxic drugs and now have peripheral neuropathy. Patients receiving other neurotoxic drugs (such as some HIV drugs) at the same time as chemotherapy. Patients with a history of diabetes mellitus and peripheral neuropathy caused by nerve compression (such as carpal tunnel or tarsal syndrome, radiculopathy, spinal stenosis, brachial plexopathy) Patients who, at the same time as chemotherapy, start taking drugs that reduce neuropathy symptoms (such as SNRI drugs) and pain relievers such as acetaminophen, pregabalin, and NSIDs, or change their amount during treatment. Patients with psychological disorders such as: severe depression, patients with suicidal thoughts, bipolar diseases Patients who consume alcohol. Patients with significant impairment of liver and kidney tests Patients who do not agree to consume rosemary extract or do not agree to participate in the study in any way. The patient is unable to tolerate rosemary extract during the study.
Age
From **25 years** old to **80 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **52**
Randomization (investigator's opinion)
Randomized
Randomization description
The sampling method in this study is a non-probability sequential method based on including and excluding criteria and until the completion of the sample volume. Allocation of samples in study groups is done by random block method. Random allocation: in order to equalize the distribution of the important confounders of gender, age and type of cancer, classes based on these variables are as follows: male class/female class, age less than 60 years/over 60 years and cancer of the esophagus, cardia, stomach, pancreas, gall bladder , small intestine, large intestine, sigmoid, rectal and anal are created and then they are placed in 2 study groups in a balanced way by block randomization.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, after meeting the including criteria's and completing the informed consent form, the patients will be randomly assigned to one of two groups A or B, and based on this grouping, the patient will be given either A or B can. Can A contains 500 mg capsules of medicine (rosemary extract) and can B contains 500 mg placebo capsules (starch). Only the main researcher is aware of the contents of cans A and B, and the nurses taking the sample and assessing the outcomes, the patients, the medical staffs and the person analyzing the data are not aware of the contents of cans A and B. In case of serious complications and questions of the attending physician, the contents of the cans will be explained to them. It is explained to the patient that he may randomly receive placebo or rosemary extract, in both cases the patient will not be deprived of his usual treatments.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic committee of Lorestan University of Medical Sciences
Street address
Shahid Rahimi hospital, Azadi square, Khorramabad
City
Khorramabad
Province
Lorestan
Postal code
6813816314
Approval date
2021-04-20, 1400/01/31
Ethics committee reference number
IR.LUMS.REC.1400.001

Health conditions studied

1

Description of health condition studied
chemotherapy induced peripheral neuropathy
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Chemotherapy induced peripheral neuropathy
Timepoint
At the beginning of the study, and then before the start of each chemotherapy session for up to two months.
Method of measurement
Based on the EORTC-CIPN20 questionnaire and measuring symptoms by a research expert based on the Total Neuropathy Score (TNS) scale.

2

Description
Severity of neuropathic pain based on Numerical Rating Scale tool
Timepoint
At the beginning of the study, and then before the start of each chemotherapy session for up to two months.
Method of measurement
Measurement of symptoms by an investigator based on the Numerical Rating Scale tool

Secondary outcomes

1

Description
Quality of life score
Timepoint
At the beginning of the study, and then before the start of each chemotherapy session for up to two months.
Method of measurement
Based on the EORTC QLQ-C30 questionnaire

Intervention groups

1

Description
Intervention group: In this group, patients are given cans containing 500 mg capsules and the patient is asked to take one oral capsule containing 500 mg of dried rosemary extract every 8 hours for two months from the second session of chemotherapy. Rosemary plant extract was prepared by the standard method at Razi Medicinal Plants Research Center in Khorramabad.
Category
Prevention

2

Description
Control group: In this group (placebo), the patient is asked to take a can containing 500 mg capsules three times a day for two months. 500 mg capsules in this group contain 500 mg of starch as a placebo. In both the intervention and placebo groups, the patient will not be deprived of any conventional treatment.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Rahimi hospital
Full name of responsible person
Shahram Ahmadi Somaghian
Street address
Safavi Ave, between Azadi square and Gap bridge, Shahid Rahimi hospital
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Email
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Web page address
http://www.rahimi.lums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Khoram-Abad University of Medical Sciences
Full name of responsible person
Bahram Rasoulian
Street address
Lorestan University of Medical Sciences, Anooshirvan Rezaei Square, Khorramabad, Lorestan, Iran
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Khorramabad
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Postal code
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Phone
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Email
international@lums.ac.ir
Web page address

http://www.lums.ac.ir/

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Khoram-Abad 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

Khoram-Abad University of Medical Sciences

Full name of responsible person

Shahram Ahmadi Somaghian

Position

Nurse

Latest degree

Master

Other areas of specialty/work

Nursery

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No. 66, Shahid Daraei Alley, Enghelab Ave, Khorramabad

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

Yahya Baharvand Iran Nia

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

Street address

The end of Honar-e-Haftom, Faze Yek, Khorramabad

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Shahram Ahmadi Somaghian

Position

Nurse

Latest degree

Master

Other areas of specialty/work

Nursery

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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

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

Yes - There is a plan to make this available

Title and more details about the data/document

All the data of this research will be shared after de-identifying people.

When the data will become available and for how long

The start of the data access period will be 6 months after the results of the data are published.

To whom data/document is available

The data of this project will be made available to all researchers and even people working in the industry upon official request.

Under which criteria data/document could be used

If the rights of the main researchers and project implementers are respected, the data of this project can be used.

From where data/document is obtainable

By e-mail to the correspondent author of the article or project manager at the following addresses: Email: shahrama20@gmail.com Mobile phone: 0098 9168608836

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

The applicant must first email his written request specifying the purpose of using the data to the project manager, then the agreement on how to use the information and respect the rights of the main project managers must be signed by the parties. After signing the contract, the data will be available to the requester in less than a month.

Comments