Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluation the efficacy of hydroalcoholic extract of Melissa officinalis L. (Dracocephalum) in chemotherapy-induced peripheral neuropathy: A double-blinded randomized placebo-controlled clinical trial

Protocol summary

Study aim

Evaluation the efficacy of hydroalcoholic extract of Melissa officinalis L. in chemotherapy-induced peripheral neuropathy

Design

This study is a randomized double blinded phase 3 clinical trial that includes control and the parallel intervention arms and will be done on 74 patients. To randomize the study, stratified block randomization (online randomization) will be applied.

Settings and conduct

This study will be done on cancer patients with chemotherapy induced peripheral neuropathy admitted to Imam Khomeini Hospital in Sari. Intervention group will receive gabapentin along with Melisa officinalis L (Dracocephalum) and the control group will receive gabapentin and placebo. Blinding will be doubled and patients, clinical care giver, and statistical analyzer will not be aware of the randomization and type of drugs.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Cancer patients (18 to 75 years old) 2- Patients who has initiated their first chemotherapy with vinca alkaloids, platinum or taxanes drivatives. 3- Patients who present neuropathy symptoms. Exclusion criteria: 1- Other possible neuropathy reasons (diabetes, thyroid function disorder, B12 deficiency or alcohol abuse) 2- Taking other drugs simultaneously to alleviate neuropathy symptoms 3- Taking any anti oxidant supplements in recent two months 4- Pregnant and nursing women

Intervention groups

Intervention group: will receive 300 mg hydroalcoholic extract of Melissa officinalis L in capsule form, twice a day beside the daily dose of 300 mg gabapentin for three months. Control group: will receive daily dose of 300 mg gabapentin as the standard treatment and also 300 mg of placebo every 12 hours for three month. Placebo is similar to the intervention drug in the appearance, color and taste.

Main outcome variables

The primary consequence variable is the chemotherapy induced peripheral neuropathy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201128049515N2**
Registration date: **2021-04-22, 1400/02/02**
Registration timing: **prospective**

Last update: **2021-04-22, 1400/02/02**
Update count: **0**

Registration date

2021-04-22, 1400/02/02

Registrant information

Name

Ramin shekarriz

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3336 4044

Email address

r.shekarriz@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-21, 1400/02/31

Expected recruitment end date

2021-08-22, 1400/05/31

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation the efficacy of hydroalcoholic extract of Melissa officinalis L. (Dracocephalum) in chemotherapy-induced peripheral neuropathy: A double-blinded randomized placebo-controlled clinical trial

Public title
Evaluation the efficacy of extract of Dracocephalum in chemotherapy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with cancer between 18 to 75 years old Patients who has received their first neurotoxic chemotherapy by using Vinca alkaloids, platinum and taxane derivatives. Patients with neuropathy symptoms.
Exclusion criteria:
Other possible reasons for neuropathy (diabetes, thyroid function disorder, B12 deficiency, alcohol abuse) Taking other medications for neuropathy symptoms simultaneously Taking any type of anti oxidant supplements in recent two months Pregnant or nursing women
Age
From **18 years** old to **75 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **74**
Randomization (investigator's opinion)
Randomized
Randomization description
To randomize the study, stratified block randomization will be applied. Patients will be divided into four groups according the medication that they are receiving: 1) Platinum drugs (cisplatin or oxaliplatin) 2) Vincristine 3) Bortezomib 4) Taxans. Then, in every category, patients will be allocated into two groups of intervention and control based on random sequence created in a quadruple manner (online randomization). Four randomized sequences of each group will be used separately by online random system. Dracocephalum and the placebo will be placed in packets based on previously defined codes and will be handed to participants based on defined randomized system.
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients grouping and the type of intervention will be known only to the primary investigator, and others (patients, fellowship colleague who will be the responsible of clinical assessments of patients, data collecting staff, the statistic analyzer and article draft writers) will not be aware of patients grouping.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mazandaran University of Medical Sciences
Street address
Vice chancellor for research and technology, Moalem Sq, Sari, Iran
City
Sari
Province
Mazandaran
Postal code
۴۸۱۵۷۳۳۹۷۱
Approval date
2021-01-27, 1399/11/08
Ethics committee reference number
IR.MAZUMS.IMAMHOSPITAL.REC.1399.077

Health conditions studied

1

Description of health condition studied
Chemotherapy induced peripheral neuropathy
ICD-10 code
G13.0
ICD-10 code description
Paraneoplastic neuromyopathy and neuropathy

Primary outcomes

1

Description
Chemotherapy induced peripheral neuropathy
Timepoint
At initial assessment and 1,2 and 3 month after initial assessment
Method of measurement

Performance status- Eastern Cooperative Oncology Group questionnaire (PS-ECOG)

Secondary outcomes

1

Description
The efficacy of treatment
Timepoint
At initial assessment of patient and 1, 2, and 3 month after the initial assessment
Method of measurement
Evaluation of neuropathy symptom alleviation and questionnaire

2

Description
Pain intensity
Timepoint
At initial assessment of patient and 1, 2, and 3 month after the initial assessment
Method of measurement
Based on visual analogue scale and questionnaire

3

Description
Adverse effects
Timepoint
At initial assessment of patient and 1, 2, and 3 month after the initial assessment
Method of measurement
Common Terminology Criteria for Adverse Events and questionnaire

4

Description
Quality of life
Timepoint
At initial assessment of patient and 1, 2, and 3 month after the initial assessment
Method of measurement
Questionnaire developed to assess the quality of life of cancer patients

Intervention groups

1

Description
Intervention group: beside the 300 mg daily dose of gabapentin will receive hydroalcoholic extract of Melissa officinalis L plant in capsule form (1 capsule containing 300 mg of the drug, 2 times a day) after each main meal, for 3 months. The plant will be provided by the medicinal herb production farm in Behshahr.
Category
Treatment - Drugs

2

Description
Control group: will receive 300 mg daily dose of gabapentin and 300 mg placebo every 12 hours for 3 month. Placebo is similar to the intervention drug in appearance, color and taste.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Ramin Shekarriz
Street address
Cancer Lab, 3rd floor, Cancer comprehensive center, Imam Khomini hospital, Amir Mazandarani Blvd, Sari Town
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Sari
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Mazandaran
Postal code
4816633131
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+98 11 3336 4044
Email
r.shekarriz@mazums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Dr. Majid Saeedi
Street address
Vice chancellor for research and technology, Moalem Sq, Sari, Iran
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+98 11 3325 7230
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source

Mazandaran 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
Mazandaran University of Medical Sciences

Full name of responsible person
Dr. Ramin Shekarriz

Position
associate professor

Latest degree
Subspecialist

Other areas of specialty/work
Oncology

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Cancer Lab, 3rd floor, Cancer comprehensive center, Imam Khomeini hospital, Amir Mazandarani Blvd, Sari Town

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Mazandaran University of Medical Sciences

Full name of responsible person
Dr. Ramin Shekarriz

Position
Associate professor

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Person responsible for updating data

Contact

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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
No - There is not 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
No - There is not 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 data will be informed to public after the deletion of participants name.

When the data will become available and for how long
After the end of the study.

To whom data/document is available
Data will be provided for researchers and industries.

Under which criteria data/document could be used
Other analysis is not authorized on data.

From where data/document is obtainable

Send your request to Dr. Ramin Shekarriz email (r.shekarriz@mazums.ac.ir) to receive datdocuments and data.

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

The request will be sent to vice chancellor for research and technology of Mazandaran University of Medical Sciences after sending to r.shekarriz@mazums.ac.ir email address and then will be assessed by the vice chancellor and the result will be informed.

Comments