

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 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 *Melissa 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 derivatives. 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

City

Sari

Province

Mazandaran

Postal code

4816633131

Phone

+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

City

Sari

Province

Mazandaran

Postal code

۴۸۱۵۷۳۳۹۷۱

Phone

+98 11 3325 7230

Email

pajoheshi@mazums.ac.ir

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
Street address
Cancer Lab, 3rd floor, Cancer comprehensive center,
Imam Khomeini hospital, Amir Mazandarani Blvd, Sari
Town
City
Sari
Province
Mazandaran
Postal code
48166234356
Phone
+98 11 3336 4044
Email
r.shekarriz@mazums.ac.ir

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
Latest degree
Subspecialist
Other areas of specialty/work
Oncology
Street address
Cancer Lab, 3rd floor, Cancer comprehensive center,
Imam Khomeini hospital, Amir Mazandarani Blvd, Sari
Town
City
Sari
Province

Mazandaran
Postal code
48166234356
Phone
+98 11 3336 4044
Email
r.shekarriz@mazums.ac.ir

Person responsible for updating data

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
Street address
Cancer Lab, 3rd floor, Cancer comprehensive center,
Imam Khomini hospital, Amir Mazandarani Blvd, Sari
Town
City
Sari
Province
Mazandaran
Postal code
4816633131
Phone
+98 11 3336 4044
Email
r.shekarriz@mazums.ac.ir

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 datadocuments 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