Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the therapeutic effect of herbal supplement (Herbal topical cream containing lavender, mint, cinnamon, ginger, moringa, poppy extract and clove extract.) in order to reduce chemotherapy-induced neuropathy, muscle pain and response to treatment

Protocol summary

Study aim

Investigating the therapeutic effect of herbal supplement (Herbal topical cream containing lavender, mint, cinnamon, ginger, moringa, poppy extract and clove extract.) in order to reduce chemotherapy-induced neuropathy, muscle pain and response to treatment

Design

A double-blind clinical trial with a control group, with parallel groups, randomized, phase 3 was conducted on 80 patients.

Settings and conduct

This study is to reduce pain caused by neuropathy and muscle pain, which will be conducted in Omid and Ghaem Hospital affiliated to Mashhad University of Medical Sciences. People receive a topical cream containing lavender, moringa, poppy extract, which is based on vaseline and ostrich oil. This study has been double-blind, which will be blind for the people participating in the study as well as the collectors.

Participants/Inclusion and exclusion criteria

Inclusion criteria. Male or female 19 to 60 years old with neuropathic pain or chronic muscle pain. Exclusion criteria: pregnant or lactating women, patients with autoimmune disorders

Intervention groups

The intervention group includes patients with neuropathic pain or chronic joint pain who receive herbal cream. The comparison group includes patients with neuropathic pain or chronic joint pain who receive placebo cream.

Main outcome variables

Educing the amount of pain caused by neuropathy and joint pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230712058750N1**
Registration date: **2023-12-29, 1402/10/08**
Registration timing: **registered_while_recruiting**

Last update: **2023-12-29, 1402/10/08**
Update count: **0**

Registration date

2023-12-29, 1402/10/08

Registrant information

Name

AMIR AVAN

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3841 6015

Email address

amir_avan@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-22, 1402/09/01

Expected recruitment end date

2025-03-19, 1403/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Investigating the therapeutic effect of herbal supplement (Herbal topical cream containing lavender, mint, cinnamon, ginger, moringa, poppy extract and clove extract.) in order to reduce chemotherapy-induced neuropathy, muscle pain and response to treatment

Public title
The effect of herbal topical cream in reducing pain caused by neuropathy and joint pain

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Patients have symptoms of chronic muscle and joint pain. Patients with neuropathic pain caused by chemotherapy

Exclusion criteria:
Pregnant or lactating woman Patients who have abdominal abscess at the time of visit. Patients with bacterial infection. Patients who use opioids on a daily basis. Possible side effects of treatment

Age
From **19 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
This randomized study will be of the block type, the type of double-blind blinding, and the method of concealing the allocation of the study will be sealed opaque envelopes, which is the SNOSE method (sequentially numbered, opaque, sealed envelopes) by one of the team members and Random numbers will be prepared and printed and will be placed inside the envelope. The door of the envelope will be closed and its contents cannot be seen from the outside. Then, first, the purpose of the study will be explained to the person who meets the specified conditions, and if the person wishes, the form will be filled. Sign the informed consent and take an envelope and then open it and enter the person in the intervention or control group based on the contents of the envelope.

Blinding (investigator's opinion)
Double blinded

Blinding description
This is a double-blind experiment that will be blind for the people participating in the study. Herbal pain reliever cream and placebo cream were prepared based on Vaseline and ostrich oil (it is the same in terms of color and shape, in order to make the aroma and smell of the placebo cream similar to the herbal cream, inside the containers before filling with the placebo cream, with a solution containing The plants and extracts used were washed).

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Medical School of Mashhad University of Medical Sciences

Street address
vakil abad sq., faculty of medicine

City
mashhad

Province
Razavi Khorasan

Postal code
9177948564

Approval date
2023-06-27, 1402/04/06

Ethics committee reference number
IR.MUMS.MEDICAL.REC.1402.185

Health conditions studied

1

Description of health condition studied
People with neuropathy or joint and muscle pain

ICD-10 code
G62.0

ICD-10 code description
Drug-induced polyneuropathy

Primary outcomes

1

Description
Pain and tingling

Timepoint
before intervention and 10 min, 1 hours , 6 hours after intervention

Method of measurement
Neuropathic Pain Scale (NPS) and Guidelines for the Pharmacological Treatment of Peripheral Neuropathic Pain: Expert Panel Recommendations for the Middle East Region

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: patients with neuropathic pain and joint pain, 50 grams of topical herbal cream, one gram of lavender, three grams of clove extract, one and a half grams of mint, two grams of cinnamon, half a gram of ginger, two tenths of grams of moringa, one cc of poppy extract of this cream. Cream based on vaseline and ostrich oil (made in Mashhad Medical Sciences Faculty) was used topically daily for 4 weeks during pain.

Category
Treatment - Drugs

2

Description
Control group: patients with neuropathic pain and joint pain used placebo cream (made in Mashhad Medical Sciences Faculty) topically daily during pain for 4 weeks.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Omid and ghaem Hospital, Mashhad University of Medical Sceinces

Full name of responsible person
Amir Avan

Street address
Medical genetics, faculty of medicine, Mashhad University of medical Sciences

City
mashhad

Province
Razavi Khorasan

Postal code
9177948564

Phone
+98 51 3800 2298

Email
avana@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Amir Avan

Street address
no 1, medical genetics, faculty of medicine, MUMS

City
mashhad

Province
Razavi Khorasan

Postal code
9177948564

Phone
+98 51 3800 2298

Email
avana@mums.ac.ir

Grant name
MUMS

Grant code / Reference number
4011572

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

Title of funding source
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
AMIR AVAN

Position
University professor

Latest degree
Medical doctor

Other areas of specialty/work
Medical Genetics

Street address
Medical genetics, faculty of medicine

City
Mashhad

Province
Razavi Khorasan

Postal code
9177948564

Phone
+98 51 3800 2298

Fax

Email
amir_avan@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
AMIR AVAN

Position
University professor

Latest degree
Medical doctor

Other areas of specialty/work
Medical Genetics

Street address
23univercity Ave,taheri5 Blvd

City
Mashhad

Province
Razavi Khorasan

Postal code
9177948564

Phone
+98 51 3841 6015

Fax

Email
amir_avan@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Amir Avan

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Genetics

Street address
No 1, medical genetics dept, faculty of medicine, ferdowsi University, mashhad

City
mashhad

Province
Razavi Khorasan

Postal code
9177948564

Phone
009838002298

Email
avana@mums.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
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
We will be ready to share all the collected de-identified paticipant data (IPD) to other researchers after the end of study.

When the data will become available and for how long
starting in January 2025

To whom data/document is available
Sharing of all collected de-identified participants data (IPD) will be started immediately after publication. people working in academic institutions or people working in businesses

Under which criteria data/document could be used
The collected de-identified participants data (IPD) will be only shared to those recipients who commit themselves to use them only for patients. They also should commit themselves to share these data with other organization only after asking permission from the original source.

From where data/document is obtainable
Data/Documents will be obtainable by sending an e-mail to avana@mums.ac.ir

What processes are involved for a request to access data/document
Data/Documents will be obtainable by sending an e-mail to avana@mums.ac.ir

Comments