Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

The effect of Crocus sativus L. (saffron) on patients with chemotherapy-induced neuropathy; A clinical trial

Protocol summary

Study aim

Using herbal compounds to chemical agents have less side effects and it is easier for patients to tolerate them.

Design

A randomized, double-blind, placebo controlled clinical trial (phase 3) with a total sample of 60 cases of cancer patients receiving chemotherapy drugs 1- A group of 20 treatment recipients receiving saffron tablets daily for a period of 3 months 2-A 20-person control group receiving a placebo per day for a period of 3 months 3. A group of 20 positive controls that receive gabapentin daily for a period of 3 months

Settings and conduct

The location of the study will be at the Kowsar Hospital of Semnan (and if necessary, other medical centers). Cancer patients who receive chemotherapy drugs are selected through a physician's history and physical examination, those who show signs of neuropathy and will be included in the study if approved. And then divided into the above mentioned groups and the mentioned protocols will be applied to them. The severity of their neuropathy symptoms will be measured by a questionnaire. In this double-blind study, both prescriber and patients will be unaware of the type of drug used.

Participants/Inclusion and exclusion criteria

Input: All cancer patients who show signs of neuropathy due to chemotherapy No entry: Cancer patients who have neuropathy due to factors other than chemotherapy, Pregnants and nursing mothers, People who receive sedatives such as morphine etc

Intervention groups

1- Treatment group receiving saffron tablets 2_ Control group receiving placebo 3. Positive control group receiving gabapentin

Main outcome variables

Severity of neuropathy (based on items in the questionnaire) of patients receiving chemotherapy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180119038433N1**
Registration date: **2018-12-28, 1397/10/07**
Registration timing: **registered_while_recruiting**

Last update: **2018-12-28, 1397/10/07**
Update count: **0**

Registration date

2018-12-28, 1397/10/07

Registrant information

Name
Amin Izadi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 23 3346 5228
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aminizadi1374@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-22, 1397/10/01

Expected recruitment end date

2019-09-22, 1398/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Crocus sativus L. (saffron) on patients with chemotherapy-induced neuropathy; A clinical trial

Public title
The effect of saffron on patients with chemotherapy-induced neuropathy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with chemotherapy-induced neuropathy
Exclusion criteria:
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization is a simple, individual and by random numbers Accidental assignment to intervention and control groups
Blinding (investigator's opinion)
Double blinded
Blinding description
Medications will be coded by a third person (outside the study) (e.g., the main treatment group number 1, placebo # 2, and positive control # 3). Then the stickers of the medications are removed and the number of drugs will be available to the student (responsible for the correct follow-up and administration of the medications). Student sees only the number and does not know the type of medicine. The patient merely knows that she will be given a study that will help her treatment and is completely unaware of the prescription of the drug. After administering the drugs and registering the data by the student, the information is provided to the statistical analyst (which he knows only the number and does not know the type of medication). After statistical analysis, the data will be available to the researcher responsible for writing the article. In order to write the article, the main researcher will also use the third person (outside the study) to match the type of medication
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee in Semnan University of Medical Sciences
Street address
Damghan road-Semnan University of Medical Sciences
City
semnan
Province
Semnan
Postal code
3519899951
Approval date
2018-11-20, 1397/08/29
Ethics committee reference number
IR.SEMUMS.REC.1397.195

Health conditions studied

1

Description of health condition studied
Chemotherapy-induced nephropathy
ICD-10 code
G62.0
ICD-10 code description
Drug-induced polyneuropathy

Primary outcomes

1

Description
Severity of neuropathy (based on items in the questionnaire) of patients receiving chemotherapy
Timepoint
Evaluation of neuropathy in patients before administration of medication is between the administration period (day 45 after the intervention, ie the administration of the first dose, placebo and positive control) and after treatment (up to 1 month after the last administration of the intervention).
Method of measurement
Nerve conduction velocity test as well as questionnaire

Secondary outcomes

1

Description
Life quality Score
Timepoint
Prior to prescribing, between the administration period (45 days after the intervention, ie the administration of the first dose, placebo and positive control) and after treatment (up to 1 month after the last administration of

the interventions)

Method of measurement

Short questionnaire 12 questions (SF12)

Intervention groups

1

Description

Patients with chemotherapy-induced neuropathy receiving a 15 mg tablet of saffron (crocin) daily up to 3 months (produced by Mashhad University of Medical Sciences)

Category

Treatment - Drugs

2

Description

Control group: Patients with chemotherapy-induced neuropathy receiving 1 placebo tablet per day for 3 months

Category

Placebo

3

Description

Control group: Patients with chemotherapy-induced neuropathy receiving a 100 mg capsule of gabapentin daily for 3 months (positive control group)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Semnan kosar hospital

Full name of responsible person

Farshid farivar

Street address

Amin highway

City

Semnan

Province

Semnan

Postal code

3519899951

Phone

+98 23 3142 2001

Email

farfarivar@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Parviz kokhaei

Street address

Bassij Blvd, Semnan University of Medical Sciences, Deputy of Research, Semnan

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Phone

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p_kokha@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Semnan 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

Semnan University of Medical Sciences

Full name of responsible person

Hooman bozorgi

Position

Assistant professor-faculty

Latest degree

Ph.D.

Other areas of specialty/work

Neuroscience

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Person responsible for scientific inquiries

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Position
Assistant professor-faculty

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Neuroscience

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available