# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 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

**Email address**

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

**City**

Semnan

**Province**

Semnan

**Postal code**

3519899951

**Phone**

+98 23 3344 0225

**Email**

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

**Street address**

Damghan road-Semnan University of Medical Sciences

**City**

Semnan

**Province**

Semnan

**Postal code**

3519899951

**Phone**

+98 23 3142 2001

**Email**

hoomanbozorgi@semums.ac.ir

## Person responsible for scientific 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

**Street address**
Damghan road-Semnan University of Medical Sciences

**City**
Semnan

**Province**
Semnan

**Postal code**
3519899951

**Phone**
+98 23 3142 2001

**Email**
hoomanbozorgi@semums.ac.ir

## Person responsible for updating data

**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

**Street address**
Damghan road-Semnan University of Medical Sciences

**City**
Semnan

**Province**
Semnan

**Postal code**
3519899951

**Phone**
+98 23 3142 2001

**Email**
hoomanbozorgi@semums.ac.ir

## 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