

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

Evaluation of the therapeutic effects of saffron (*Crocus sativus*) on clinical and electrodiagnostic symptoms of patients with type 2 diabetes: a double-blind clinical trial

Protocol summary

Study aim

Evaluation of the therapeutic effects of saffron (*Crocus sativus*) on clinical and electrodiagnostic symptoms of patients with type 2 diabetes: a double-blind clinical trial

Design

This phase 3 study is a placebo-controlled, double-blind, randomized controlled trial will be performed on 60 individuals with type 2 diabetes. Block randomization will be used

Settings and conduct

This study will be performed in Imam Reza Hospital of Tabriz University of Medical Sciences. A demographic information questionnaire will be used. intervention will be given to participants at each visit to be taken every 12 hours. In addition to taking these capsules, people will not stop taking diabetes medications. Also, all variables of this study will be evaluated at the beginning and end of the 3-month period. According to the double-blind nature of this study, a person who has no role in the intervention performs randomization and assigns patients to intervention or placebo groups based on the random sequence. Another person who is unaware of patient allocation proscribes drugs according to codes. This randomization and assignment of codes will be remained hidden from researchers and participants until the statistical analysis is completed.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Age more than 18 years Recent diagnosis (maximum 3 months) of type 2 diabetes Willingness to participate in the study Exclusion criteria: Having type 1 diabetes Gestational diabetes or other specific types of diabetes Insulin therapy over the past three months

Intervention groups

The saffron group will receive 100 mg of saffron daily for 3 months, and the placebo group will receive 2 placebo capsules daily for 3 months.

Main outcome variables

clinical and electrodiagnostic of neuropathy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100127003217N13**

Registration date: **2020-12-04, 1399/09/14**

Registration timing: **prospective**

Last update: **2020-12-04, 1399/09/14**

Update count: **0**

Registration date

2020-12-04, 1399/09/14

Registrant information

Name

Fariba Eslamian

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 41 3337 3967

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-21, 1399/10/01

Expected recruitment end date

2021-12-22, 1400/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the therapeutic effects of saffron (*Crocus sativus*) on clinical and electrodiagnostic symptoms of patients with type 2 diabetes: a double-blind clinical trial

Public title

Evaluation of the therapeutic effects of saffron on clinical and electrodiagnostic symptoms of patients with type 2 diabetes

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Having type 2 diabetes Symptoms of sensory neuropathy such as numbness, burning and pain, muscle weakness, atrophy and balance disorders Age more than 18 years Body mass index (BMI) 18.5–35 kg / m Recent diagnosis (maximum 3 months) of type 2 diabetes Willingness to participate in the study

Exclusion criteria:

Having type 1 diabetes Gestational diabetes or other specific types of diabetes Insulin therapy over the past three months Having serious gastrointestinal (GI) diseases including peptic ulcers and gastrointestinal bleeding Having an autoimmune disease Osteoarthritis (due to masking the symptoms of neuropathy) Having a history of inherited neuropathy Chronic uremia Allergy to saffron Use of drugs that affect on the symptoms of neuropathy such as antidepressants and anticonvulsants

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation will performed using random blocking with block sizes 10 and 1: 1 assignment ratio using Random allocation software (RAS) software

Blinding (investigator's opinion)

Double blinded

Blinding description

According to the double-blind nature of this study, a person who has no role in the intervention performs randomization and assigns patients to intervention or placebo groups based on the random sequence . Another person who is unaware of patient allocation proscribes drugs according to codes. This randomization and assignment of codes will remain hidden from researchers

and participants until the statistical analysis is completed.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tabriz University of Medical Sciences

Street address

Golgasht St. / Tabriz University of Medical Sciences, Central Building No. 2 / Third Floor

City

Tabriz

Province

East Azarbaijan

Postal code

5165665931

Approval date

2020-10-26, 1399/08/05

Ethics committee reference number

IR.TBZMED.REC.1399.734

Health conditions studied**1****Description of health condition studied**

type 2 diabetes

ICD-10 code

E08.40

ICD-10 code description

Diabetes mellitus due to underlying condition with diabetic neuropathy, unspecified

Primary outcomes**1****Description**

Reduction on the risk of clinical symptoms of neuropathy

Timepoint

before intervention and 3 months after intervention

Method of measurement

Michigan Questionnaire

2**Description**

Changes in electrodiagnostic of neuropathy

Timepoint

before intervention and 3 months after intervention

Method of measurement

Electromyography

Secondary outcomes

1

Description

Changes in laboratory parameters associated with type 2 diabetes

Timepoint

before intervention and 3 months after intervention

Method of measurement

Calorimetric enzymatic

Intervention groups

1

Description

Intervention group: Treatment group will receive daily two capsules containing aqueous extract of saffron (50 mg) orally which will be prepared in the geriatrics center for 3 months .

Category

Treatment - Drugs

2

Description

Control group: Placebo group will receive daily two capsules containing cornstarch flours orally which will be prepared in the geriatrics center for 3 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam reza Hospital

Full name of responsible person

Fariba Eslamiyan

Street address

Imam Reza Hospital, The end of Golgasht St, Daneshgah St

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5166614756

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eslamiyanf@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

dr Mohammad Samiei

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Samiei.moh@gmail.com

Grant name

Grant code / Reference number

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

No

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Fariba Eslamiyan

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity
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Arezou Aminzadeh
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work

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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

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

Not applicable

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

IPD collected for the primary outcome measure only

When the data will become available and for how long

starting in March 2022

To whom data/document is available

only available for people working in academic institutions

Under which criteria data/document could be used

For Meta-analysis only

From where data/document is obtainable

دکتر فریبا اسلامیان: Eslamiyanf@tbzmed.ac.ir

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

Will be done for documented and registered requests

Comments