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 3study 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 numbless, 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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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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5166614756

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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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Full name of responsible person
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Position
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Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

Contact
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Full name of responsible person
Arezou Aminzadeh
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Physical Medicine
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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