Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Jul 2026

Comparison of the effect of oral Zingiber officinale supplement and placebo on some inflammatory factors and lipid profile and anthropometric measures in diabetic hemodialysis patients: A double blind randomized clinical trial

Protocol summary

Study aim
To determine the effect of oral Zingiber officinale supplement supplement on some inflammatory factors, lipid profile and anthropometric measures in hemodialysis patients with diabetes.

Design
Clinical trials have two intervention and control groups, with parallel, double blind, randomized on 44 patients. Eligible individuals will be randomly assigned to one of the intervention or control groups based on the blocks created by the RAS random allocation software.

Settings and conduct
In the clinical trial among the patients undergoing dialysis with diabetes in the dialysis center of Imam Reza Hospital in Tabriz, 44 eligible patients will be selected. Random codes created by the RAS software. Sealed closed envelopes containing random codes (A or B) will be used to assign subjects to either the intervention group or the control group by the randomization coordinator of the study. Both the investigator and the patients will be blind to the treatment allocation.

Participants/Inclusion and exclusion criteria
Inclusion criteria: diabetic patients undergoing hemodialysis who have been on dialysis for at least 3 months; Two or three dialysis sessions a week, The duration of each session dialysis is 4 hours; Patients who desire to enter the study, Patients over 18 years of age. Non-inclusion criteria: History of acute gastrointestinal disease; Thyroid disorders; Gallstones,Consumption of fish oil supplement, Consumption steroidal and non-steroidal anti inflammatory drugs; Levothyroxine; Warfarin; Anti oxidant supplements; Ginger allergy

Intervention groups
Intervention group: will consume 4 capsules of zingiber officinale daily. (placebo) control group: Take 4 capsules containing corn starch daily.

Main outcome variables
Inflammatory factors (hs-CRP, IL6, PLR, NLR), lipid profile (LDL, HDL, TG, TC) and anthropometric measurement (BMI, weight and waist circumference to hip circumference)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191109045382N3**
Registration date: **2020-07-17, 1399/04/27**
Registration timing: **registered_while_recruiting**

Last update: **2020-07-17, 1399/04/27**
Update count: **0**

Registration date
2020-07-17, 1399/04/27

Registrant information

Name
Zohreh Ghoreishi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 41 3333 1712

Email address
ghoreyshiz@tbzmed.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-02-09, 1398/11/20

Expected recruitment end date
2020-09-10, 1399/06/20
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of oral Zingiber officinale supplement and placebo on some inflammatory factors and lipid profile and anthropometric measures in diabetic hemodialysis patients: A double blind randomized clinical trial

Public title
The effect of oral Zingiber officinale supplement in diabetic in hemodialysis patients with diabetes
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Diabetic patients undergoing hemodialysis who have been on dialysis for at least 3 months Two or three dialysis sessions a week The duration of each session dialysis is 4 hours Patients who desire to enter the study Patients over 18 years of age
Exclusion criteria:
History of acute gastrointestinal disease History of Thyroid disorders History of gallstones Consumption of fish oil supplement Consumption steroid and non-steroidal anti-inflammatory drugs Consumption of Levothyroxine Consumption of Warfarin Consumption of antioxidant supplements History of ginger allergy Smoking
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **44**
Randomization (investigator's opinion)
Randomized
Randomization description
The study is a double-blind control clinical trial. 44 eligible patients will be randomly assigned to one of the intervention or control groups. Random codes created by the RAS (Random allocation software) software. Sealed closed envelopes containing random codes (A or B) will be used to assign subjects to either the intervention group or the control group by the randomization coordinator of the study. Both the investigator and the patients will be blind to the treatment allocation.
Blinding (investigator's opinion)
Double blinded
Blinding description
In the present study, participants and researchers during the study did not know whether each individual would be in the intervention or control group. For blinding, ginger and placebo capsules will be similar in appearance, packaging and labeling. The capsules are prepared by the researcher with a capsule filling device. For this double blind study, at the start of the study, a set of bottles containing capsule is encoded A and B, by a person other than the researcher so that the researcher is not aware of the type of capsules received by each group.
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
Tabriz University of Medical Sciences, Attar Neishabouri avenue, Golgasht street.
City
Tabriz
Province
East Azarbaijan
Postal code
5166/15731
Approval date
2020-02-04, 1398/11/15
Ethics committee reference number
IR.TBZMED.REC.1398.1186

Health conditions studied

1

Description of health condition studied
Diabetic hemodialysis
ICD-10 code
E11.22
ICD-10 code description
Type 2 diabetes mellitus with diabetic chronic kidney disease

Primary outcomes

1

Description

Cholestrol

Timepoint

At the beginning of the study and 8 weeks after intervention

Method of measurement

Measurement of Cholesterol by enzymatic method

2

Description

Triglyceride

Timepoint

At the beginning of the study and 8 weeks after intervention

Method of measurement

Measurement of Triglycerides by enzymatic method

3

Description

Low density lipoprotein (LDL)

Timepoint

At the beginning of the study and 8 weeks after intervention

Method of measurement

LDL measurement by enzymatic method

4

Description

High density lipoprotein (HDL)

Timepoint

At the beginning of the study and 8 weeks after intervention

Method of measurement

Measurement of HDL by enzymatic method

5

Description

Anthropometric measure

Timepoint

At the beginning of the study and 8 weeks after intervention

Method of measurement

Height measurement with a meter and weight measurement with a scale

6

Description

Level of high sensivity C-reactive protein (hs-CRP) inflammatory factor

Timepoint

At the beginning of the study and 8 weeks after intervention

Method of measurement

Measurement of hs-CRP by immuno-turbidimetric method

7

Description

Level of Interleukine-6 (IL-6) inflammatory factor

Timepoint

At the beginning of the study and 8 weeks after intervention

Method of measurement

Measurement of IL6 with ELISA kit

8

Description

Platelet lymphocyte ratio (PLR)

Timepoint

At the beginning of the study and 8 weeks after intervention

Method of measurement

Measurement of PLR by CBC test

9

Description

Neutrophil lymphocyte ratio (NLR)

Timepoint

At the beginning of the study and 8 weeks after intervention

Method of measurement

Measurement of NLR by CBC test

Secondary outcomes

1

Description

Intake calories and macronutrients

Timepoint

At the beginning of the study and 8 weeks after intervention

Method of measurement

Recall and record food Questionnaires

Intervention groups

1

Description

Intervention group: Patients in this group will take 4 ginger capsules 500 mg daily (prepared by the researcher or capsule filling machine) for 8 weeks.

Category

Treatment - Drugs

2

Description

Control group: In this group, patients take 4 corn starch capsules daily, which are prepared in the same shape and size as the drug casules, which will be consumed for 8 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Reza Medical Research & Training Hospital
Full name of responsible person
Dr. Zohreh Ghoreyshi
Street address
Imam Reza Medical Research Training Center, Daneshgah street
City
Tabriz
Province
East Azarbaijan
Postal code
5166614711
Phone
+98 41 3336 2117
Email
ghoreyshiz@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
Street address
Vice Chancellor for Research No 2 Central Building, Tabriz University of Medical Sciences, Daneshgah Street
City
Tabriz
Province
East Azarbaijan
Postal code
5166614711
Phone
+98 41 3335 7581
Email
ghoreyshiz@tbzmed.ac.ir

Grant name

Grant code / Reference number

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

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
Parisa veisi
Position
M.Sc student Of Clinical Nutrition
Latest degree
Bachelor
Other areas of specialty/work
Nutrition
Street address
Faculty of Nutrition and Food Sciences, Attar Neishabouri avenue, Golgasht street
City
Tabriz
Province
East Azarbaijan
Postal code
5166614711
Phone
+98 41 3340 8619
Email
parisaveisi1995@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr. Zohreh Ghoreyshi
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Faculty of Nutrition and Food Sciences, Attar Neishabouri avenue, Golgasht street
City
Tabriz
Province
East Azarbaijan
Postal code
5166614711
Phone
+98 41 3336 2117
Email
ghoreyshiz@tbzmed.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Zohreh Ghoreyshi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Faculty of Nutrition and Food Sciences, Attar Neishabouri avenue, Golgasht street

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Phone

+98 41 3336 2117

Email

ghoreyshiz@tbzmed.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

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

Title and more details about the data/document

Data collected for the primary outcomes will be shared.

When the data will become available and for how long

Accessibility to data is possible 8 months after publication.

To whom data/document is available

The data will only be available for people working in academic institutions.

Under which criteria data/document could be used

The data of the present study will only be accessible by other researchers, for conducting Meta analysis.

From where data/document is obtainable

Dr. Zohreh Ghoreyshi, Faculty of Nutrition and Food Sciences, Tabriz University of Medical Sciences Email: ghoreyshiz@tbzmed.ac.ir phone number: 0098 912 739 0799

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

The applicator can send a request to the person responsible for the study by email and within 10 days the document will be sent to the requesting person.

Comments