

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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 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

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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

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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

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Email

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Dr. Zohreh Ghoreyshi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for updating data

Contact

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Full name of responsible person

Dr. Zohreh Ghoreyshi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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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

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