Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Aug 2026

Comparison of the effect of oral zingiber officinale supplement and placebo on pre-oxidant-antioxidant balance and glycemic control in diabetic hemodialysis patients: A double blind randomized clinical trial

Protocol summary

Study aim

To determine the effect of oral zingiber officinale supplement on the Prooxidant-antioxidant balance, Glycemic varaiables and renal function indicators in hemodialysis patients with diabetes.

Design

Clinical trials have two intervention and control groups, with parallel, double blind, randomized, phase 3 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

The trial will be conducted at dialysis center of Imam Reza hospital affiliated to Tabriz University of Medical Sciences, Iran. All the patients will be randomly assigned to one of the two supplement or placebo groups.The boxes containing ginger and placebo capsules will be coded by the person responsible for preparing them, and the main investigators and the patients will be blinded to the type of supplement each group receives.

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; History of Thyroid disorders; History of gallstones; Consumption of fish oil supplement; Consumption steroid and non-steroidal anti-inflammatory drugs.

Intervention groups

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

Main outcome variables

Prooxidant-antioxidant balance(PAB), Level of fasting blood sugar(FBS),Level of insulin ,HOMA-IR scores

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191109045382N2**
Registration date: **2020-07-06, 1399/04/16**
Registration timing: **registered_while_recruiting**

Last update: **2020-07-06, 1399/04/16**
Update count: **0**

Registration date

2020-07-06, 1399/04/16

Registrant information

Name

Zohreh Ghoreishi

Name of organization / entity

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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 pre-oxidant-antioxidant balance and glycemic control in diabetic hemodialysis patients: A double blind randomized clinical trial

Public title
The effect of oral zingiber officinale supplement 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
Eligible individuals will be randomly assigned to one of the intervention or control groups, which will be randomly assigned based on the blocks created by the RAS software.

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 Neyshabouri 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.1398.1188

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
Prooxidant-antioxidant balance (PAB)

Timepoint
At the beginning of the study and 8 weeks after intervention

Method of measurement
Measurement by biochemical method and by ELISA kit

2

Description
Level of fasting blood sugar (FBS)

Timepoint

At the beginning of the study and 8 weeks after intervention

Method of measurement

Measurement of fasting blood sugar (FBS) by enzymatic method

3

Description

Level of insulin

Timepoint

At the beginning of the study and 8 weeks after intervention

Method of measurement

Measurement of insulin by enzymatic method

4

Description

HOMA-IR scores

Timepoint

At the beginning of the study and 8 weeks after intervention

Method of measurement

Measurement of HOMA-IR score using formula

Secondary outcomes

1

Description

Serum urea levels

Timepoint

At the beginning of the study and 8 weeks after intervention

Method of measurement

Measurement of serum urea level by enzymatic method

2

Description

Serum creatinine level

Timepoint

At the beginning of the study and 8 weeks after intervention

Method of measurement

Measurement of serum creatinine level by enzymatic method

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 capsules and 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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
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Person responsible for updating data

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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