Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of zingiber on glucose and proteinuria in type2 diabetic patients

Protocol summary

Summary

Objective: Evaluation the effect of ginger on urine protein and urine glucose in type 2 diabetic patients. Design of the study: randomized (six-block method), double-blind study, control with placebo, single arm trial Experimental population: Type 2 diabetic patients which referring to Endocrine clinic of Semnan University of medical sciences. Inclusion Criteria: At least 18 years old; Diabetic patients treated with insulin or glucose lowering drugs Exclusion criteria: Pregnant or lactating women with diabetes; alcoholic; liver disease; symptomatic gallstone; kidney disease; active malignancy; acute infection and warfarin users. Sample size, intervention, intervention time and outcome of study: The sample size of this study is 100 patients which divided into intervention and control groups. Intervention group: 50 patients in the intervention group receiving 1600 mg of ginger (an 800 mg capsule) daily, before lunch and before dinner, for 12 weeks. Control group: 50 patients in the control group receiving daily 1600 mg placebo (an 800 mg capsule containing wheat flour), before lunch and before dinner, for 12 weeks. In this study, Ginger and Placebo capsules are prepared and coded without the knowledge of the prescribers, and after the completion of the study, the capsule code will be provided by the pharmaceutical company to determine which of the patients used Ginger or placebo. Before and after intervention, blood glucose and 24-hour urine protein content are measured in both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017103025732N27**
Registration date: **2017-11-01, 1396/08/10**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-11-01, 1396/08/10

Registrant information

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Alireza Emadi
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Semnan University of Medical Sciences, Semnan, Iran
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+98 23 3345 1336
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are20935@semums.ac.ir

Recruitment status

Recruitment complete

Funding source

Semnan University of Medical Sciences

Expected recruitment start date

2017-02-28, 1395/12/10

Expected recruitment end date

2017-09-01, 1396/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of zingiber on glucose and proteinuria in type2 diabetic patients

Public title

Effect of zingiber on glucose and proteinuria in type2 diabetic patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria: At least 18 years old; Diabetic patients treated with insulin or glucose lowering drugs Exclusion

criteria: Pregnant or lactating women with diabetes; alcoholic; liver disease; symptomatic gallstone; kidney disease; active malignancy; acute infection and warfarin users.

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee, Semnan University of Medical Sciences

Street address
Semnan University of Medical Sciences, Basij Blvd, Semnan

City
Semnan

Postal code
3514799442

Approval date
2010-09-23, 1389/07/01

Ethics committee reference number
IR.SEMUMS.REC.1395.207

Health conditions studied

1

Description of health condition studied
Type 2 diabetes

ICD-10 code
E11

ICD-10 code description
Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description
24-hour urine protein

Timepoint
Before and after the intervention

Method of measurement
the experiment

2

Description
Blood sugar

Timepoint
Before and after the intervention

Method of measurement
the experiment

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 50 patients in the intervention group receiving 1600 mg of ginger (an 800 mg capsule) daily, before lunch and before dinner, for 12 weeks.

Category
Treatment - Drugs

2

Description
Control group: 50 patients in the control group receiving daily 1600 mg placebo (an 800 mg capsule containing wheat flour), before lunch and before dinner, for 12 weeks.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Endocrinology Clinic, Semnan University of Medical Sciences

Full name of responsible person
Maliheh Yarmohamadi

Street address
17 shahrivar Blvd, Semnan

City
Semnan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Deputy of Research and Technology, Semnan University of Medical Sciences
Full name of responsible person
Mohammadreza Asgari
Street address
Semnan University of Medical Sciences, Basij Blvd, Semnan
City
Semnan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Deputy of Research and Technology, Semnan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty