Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Oct 2026

Study of the effect of ginger on biochemical markers and imaging of non-alcoholic fatty liver disease (NAFLD) in patients with type 2 diabetes mellitus.

Protocol summary

Study aim

The perpose of this study is to evaluate the effects of ginger on biochemical parameters and imaging findings of non-alcoholic fatty liver in patients with type 2 diabetes.

Design

This study is a randomized, double-blind, parallel clinical trial conducted on seventy non-alcoholic fatty liver disease in diabetic patients (type 2) who were referred to Shahid Motahari clinic in Shiraz in 1397.

Settings and conduct

The study population included 70 type 2 diabetic patients with non-alcoholic fatty liver disease referred to Shahid Motahari clinic (affiliated to Shiraz University of Medical Sciences).

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1) Patients with controlled type 2 diabetes mellitus. 2) Fasting blood glucose is between 80 and 130 and HbA1C is less than 7%. 3) Age range 20 to 65 years 4) Body mass index (BMI) ranges from 18 to 35 kg/m2 5) The serum alanine transaminase level (ALT) is more than one and a half times higher than normal (ie, in men more than 45 and in women more than or equal to 29 units per liter according to the latest definition of abnormal ALT in men and women) 6) Having fatty liver disease (moderate to high) in liver ultrasound 7) Informed consent to participate in the study Exclusion criteri: 1) Pregnancy 2) Liver failure (acute or chronic) 3) Liver diseases such as autoimmune hepatitis, viral hepatitis B and C (active or inactive), Wilson's disease and ... 4) Hypo and hyperthyroidism 5) Renal failure (creatinine above 1.5 mg / dL) 6) Diabetic retinopathy 7) Diabetic Nephropathy 8) alcohol consumption 9) Any malignancy (treated or not) 10) Taking warfarin 11) Taking contraceptives, ursodeoxycholic acid, glucocorticoids, statins, probiotics, vitamin E in the last three months 12) History of allergy to ginger 13) Heart disease 14) History of allergy

Intervention groups

- Intervention group: Capsules containing ginger powder (500 mg) three times daily, half an hour after meal, for 3 months. - Placebo group (Control): Capsules (with the same shape, odor and color as intervention group) containing 500 mg of starch and ginger powder in a weight ratio of 1:10) three times daily, half an hour after meal, for 3 months. - All patients are advised to limit carbohydrate intake and daily physical activity for weight loss.

Main outcome variables

Weight and Body Mass Index (BMI), Abdominal circumference and hip circumference, Fasting Blood Glucose (FBS), Glycosylated hemoglobin (Hb-A1C), Serum triglyceride, serum cholesterol, Serum levels of alanine aminotransferase (ALT), serum levels of aspartate aminotransferase (AST), Gamma glutamyltransp peptidase (GGT), Tumor necrosis factor-alpha (TNF-α), C- Reactive Protein (CRP), Liver fibrosis and ultrasound findings, Insulin resistance index, serum creatinine.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140307016876N3**
Registration date: **2018-02-25, 1396/12/06**
Registration timing: **prospective**

Last update: **2018-02-25, 1396/12/06**
Update count: **0**

Registration date

2018-02-25, 1396/12/06

Registrant information

Name

Mesbah Shams

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 4316

Email address

shams@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-06, 1396/12/15

Expected recruitment end date

2019-02-19, 1397/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the effect of ginger on biochemical markers and imaging of non-alcoholic fatty liver disease (NAFLD) in patients with type 2 diabetes mellitus.

Public title

The effects of ginger on fatty liver in type 2 diabetic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The patient with type 2 diabetes mellitus Fasting blood sugar between 80 and 130 and HbA1C is less than 7% Age range 25 to 65 years Body mass index (BMI) ranges from 22 to 35 kg / m 2 The serum alanine transaminase level (ALT) is more than one and a half times higher than normal (ie, in men more than 45 and in women more than or equal to 29 units per liter according to the latest definition of abnormal ALT in men and women) Having a high-fatty liver disease (moderate to high) in liver ultrasound Conscious informed consent of patients to participate in the study

Exclusion criteria:

Pregnancy Liver failure (acute or chronic) Hepatitis such as autoimmune hepatitis, viral hepatitis B and C (active or inactive), Wilson's disease and ... Hypo and hyperthyroidism Renal failure (creatinin above 1.5 mg / dL) Diabetes-induced retinopathy Diabetic Nephropathy alcohol consumption Any malignancy (treated or not) Taking warfarin Taking contraceptives, ursodeoxycholic acid, glucocorticoids, statins, probiotics, vitamin E in the last three months History of allergy to ginger Addiction and drug abuse Heart disease History of allergy

Age

From **25 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Seventy diabetic patients with inclusion criteria who have fatty liver in ultrasound that graded based on the Saverymuttu Scoring System by a radiologist will enter the stydy. After justifying them to the study and obtaining written informed consent will be divided in two groups of 35 patients, A and B with use of random numbers.

Blinding (investigator's opinion)

Double blinded

Blinding description

Medication is made by a personal centre that has no relation with the patients and the research team and from the beginning, it is classified into two groups A and B with a completely similar appearance. The patients are also fully aware of the way the program is performed, but they do not know whether they are receiving the main medicine or the placebo. And the researcher who is related to the patients, as well as physicians who perform paraclinical and therapeutic procedures of the patients are not aware of which group of patients are in the intervention, as well as the collector information and data and statistics consultant are not aware of the content of these two groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee on Research in Shiraz Medical School

Street address

Shiraz Medical School, Zand Ave., Imam Hossein Square

City

Shiraz

Province

Fars

Postal code
7134845794
Approval date
2017-11-13, 1396/08/22
Ethics committee reference number
IR.SUMS.MED.REC.1396.90

Health conditions studied

1

Description of health condition studied
Non-alcoholic fatty liver disease (NAFLD) in patients with type 2 diabetes mellitus.
ICD-10 code
K76.0
ICD-10 code description
Fatty (change of) liver, not elsewhere classified

2

Description of health condition studied
Type 2 diabetes mellitus
ICD-10 code
E11
ICD-10 code description
Type 2 diabetes mellitus

Primary outcomes

1

Description
Liver aminotrransferase (ALT) Level
Timepoint
Before intervention and three months after the intervention
Method of measurement
Colorimetric method

2

Description
Liver fibrosis
Timepoint
Before and three months after the intervention
Method of measurement
Fibrosan (ultrasound waves)

Secondary outcomes

1

Description
Weight
Timepoint
Before the intervention and three months after the intervention began
Method of measurement
Balance

2

Description
Body Mass Index (BMI)
Timepoint
Before the intervention and three months after the intervention began
Method of measurement
Formula: Weight (Kg)/(Height)(m)2

3

Description
Abdominal circumference
Timepoint
Before the intervention and three months after the intervention began
Method of measurement
Tape measure

4

Description
Hip circumference
Timepoint
Before the intervention and three months after the intervention began
Method of measurement
Tape measure

5

Description
Insulin resistance index
Timepoint
Before the intervention and three months after the intervention began
Method of measurement
Homeostasis model assessment (HOMA-IR)

6

Description
Glycosylated hemoglobin (HbA1C)
Timepoint
Before the intervention and three months after the intervention began
Method of measurement
HPLC

7

Description
Fasting Blood Sugar (FBS)
Timepoint
Before the intervention and three months after the intervention began
Method of measurement
Enzymatic method

8

Description
Serum triglyceride (TG)

Timepoint
Before the intervention and three months after the intervention began
Method of measurement
Enzymatic method

9

Description
Serum Cholesterol (Chol)
Timepoint
Before the intervention and three months after the intervention began
Method of measurement
Colorimetric method

10

Description
Serum levels of aspartate aminotransferase (AST)
Timepoint
Before the intervention and three months after the intervention began
Method of measurement
Colorimetric method

11

Description
Serum level of gamma glutamyltransp peptidase (GGT)
Timepoint
Before the intervention and three months after the intervention began
Method of measurement
Colorimetric method

12

Description
Serum creatinine level
Timepoint
Before the intervention and three months after the intervention began
Method of measurement
Colorimetric method

13

Description
Tumor necrosis factor-alpha (TNF-α)
Timepoint
Before the intervention and three months after the intervention began
Method of measurement
ELISA (Enzyme Linked Immuno Sorbent Assay)

14

Description
high sensitive C-reactive protein (hsCRP)
Timepoint
Before the intervention and three months after the intervention began
Method of measurement
ELISA (Enzyme linked Immunosorbent assay)

Intervention groups

1

Description
Capsule containing ginger powder (500 mg) three times daily, half an hour after meal for 3 months.
Category
Treatment - Drugs

2

Description
Capsule containing 500 mg of starch powder and ginger with a ratio of 1:10 three times daily, half an hour after meal for 3 months.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Motahari Clinic
Full name of responsible person
Parissa Sadat Ghoreishi
Street address
Specialized clinic of Shahid Motahari , Namazi Square, Zad Ave.
City
Shiraz
Province
Fars
Postal code
7193711351
Phone
+98 71 3612 1000
Email
drghoreishi@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Vice Chancellor of Research
Street address
Traditional Medicine Research Center, School of Medicine
City
Shiraz
Province
Fars
Postal code

Phone
+98 71 3233 7589
Email
salehialireza45@yahoo.com

Grant name

Grant code / Reference number

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

Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Parissa Sadat Ghoreishi
Position
Ph.D.student of Iranian Traditional Medicine
Latest degree
Medical doctor
Other areas of specialty/work
Traditional Medicine
Street address
Traditional Medicine Department, Faculty of Medicine, Imam Hossein Square, Zand Ave.
City
Shiraz
Province
Fars
Postal code
7134845794
Phone
+98 71 3234 5145
Email
drghoreishi@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Mesbah Shams
Position
Associate Professor of Internal Medicine and Endocrinology
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
Street address
Endocrine and Metabolism Research Center, Nemazee Hospital, Shiraz
City
Shiraz
Province
Fars
Postal code
7193711351
Phone
+98 71 3647 4316
Email
shams@sums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Mesbah Shams
Position
Associate Professor of Internal Medicine and Endocrinology
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
Street address
Endocrine and Metabolism Research Center, Nemazee Hospital, Shiraz
City
Shiraz
Province
Fars
Postal code
7193711351
Phone
+98 71 3647 4316
Email
shams@sums.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
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
No - There is not 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

Primary outcome measures

When the data will become available and for how long

3 months after publication

To whom data/document is available

People working in academic institutions

Under which criteria data/document could be used

From where data/document is obtainable

Email: shams@sums.ac.ir

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

After evaluation of the request

Comments