

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

The effect of Sour tea supplementation on liver enzymes, total antioxidant capacity, glycemic indicator, lipid profile and sonographic outcomes in patients with nonalcoholic fatty liver disease: A randomized controlled trial.

Protocol summary

Study aim

We aim to explore the effects of sour tea supplementation on NAFLD patients.

Design

This is a parallel double-blinded, randomized, placebo controlled trial.

Settings and conduct

Data collection will be conducted in the specialist's clinic of Khorshid hospital of Isfahan. 70 Participants who definitely diagnose to have NAFLD will allocate into 2 groups of 35 subjects, one group will be the intervention and the other group will be the control group. Intervention group will take 500 mg of sour tea tablets, and control group will take placebo tablets with identical appearance for 8 weeks. At the beginning of the study, a blood sample and sonographic liver assessments will be derived from all patients. Outcomes of the disease will be compared by a blood sample test and liver sonographic assessments, after 8-weeks of interventions.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with the nonalcoholic fatty liver disease confirmed with imaging techniques.
exclusion criteria: Alcohol consumption; Pregnant and lactating women; Any known forms of hepatic or metabolic disease except Non alcoholic fatty liver disease; Using antioxidant supplements; Hormone Therapy.

Intervention groups

Intervention group will take 500 mg of sour tea tablets, and control group will take placebo tablets with identical appearance containing starch for 8 weeks.

Main outcome variables

liver enzymes, lipid profile, Sonographic outcomes, Fasting blood sugar, Total antioxidant capacity.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140208016529N3**

Registration date: **2018-10-24, 1397/08/02**

Registration timing: **retrospective**

Last update: **2018-10-24, 1397/08/02**

Update count: **0**

Registration date

2018-10-24, 1397/08/02

Registrant information

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Mohammad hassan Entezari

Name of organization / entity

Isfahan university of medical sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-23, 1397/05/01

Expected recruitment end date

2018-10-23, 1397/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Sour tea supplementation on liver enzymes, total antioxidant capacity, glycemic indicator, lipid profile and sonographic outcomes in patients with nonalcoholic fatty liver disease:A randomized controlled trial.

Public title

The effect of Sour tea supplementation in nonalcoholic fatty liver disease.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with the nonalcoholic fatty liver disease confirmed with imaging techniques. Body Mass Index (BMI) of them is greater than 24.9 and lower than 40.

Exclusion criteria:

Alcohol consumption Pregnant and lactating women Any known forms of hepatic or metabolic disease except NAFLD, such as hereditary hemochromatosis, Wilson's disease, cirrosis, other metabolic disease history of gastric bypass or intestine surgery Taking hepatotoxic drugs such as calcium channel blocker, methotrexate, amiodarone, chloroquine and anti inflammatory drugs Using antioxidant supplements Hormone Therapy Patients with a history of Cushing's syndrome renal failure Participants with less than 80% are going to be excluded.

Age

From **23 years** old to **55 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Subjects will be allocating into intervention or placebo group by permuted block randomization method.

Blinding (investigator's opinion)

Double blinded

Blinding description

Sour tea supplement and placebo will have identical appearance.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethic Committee of Isfahan University of Medical Sciences

Street address

Department of Clinica Isfahan University of Medical Sciences, Hezar Jarib Street, Isfahan

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Postal code

8174673461

Approval date

2018-03-04, 1396/12/13

Ethics committee reference number

IR.MUI.REC.1396.2.137

Health conditions studied**1****Description of health condition studied**

Nonalcoholic Fatty Liver Disease.

ICD-10 code

K75.81

ICD-10 code description

Nonalcoholic steatohepatitis (NASH)

Primary outcomes**1****Description**

Liver enzymes (ALT, AST)

Timepoint

The first day of the study and the last day of 8th week

Method of measurement

Using Microgram/ml - laboratory kit

2**Description**

Lipid profile (TG, HDL, Total cholestrol)

Timepoint

The first day of the study and the last day of 8th week

Method of measurement

laboratory kit

3**Description**

Liver steatosis index

Timepoint

The first day of the study and the last day of 8th week

Method of measurement

Sonography

4

Description

Fasting blood sugar

Timepoint

The first day of the study and the last day of 8th week

Method of measurement

laboratory kit

5

Description

Total antioxidant capacity

Timepoint

The first day of the study and the last day of 8th week

Method of measurement

laboratory kit

Secondary outcomes

1

Description

Waist to hip ratio

Timepoint

The first day of the study and the last day of 8th week

Method of measurement

Non-stretchable tape without any pressure

2

Description

Body Mass Index (BMI)

Timepoint

The first day of the study and the last day of 8th week

Method of measurement

Weight (kilograms) divided by the square of height (meters)

3

Description

Systolic and diastolic blood pressure

Timepoint

The first day of the study and the last day of 8th week

Method of measurement

By mercury sphygmomanometer

Intervention groups

1

Description

Intervention group will take 500 mg of sour tea tablets, for 8 weeks.

Category

Treatment - Drugs

2

Description

Control group will take placebo tablets with identical appearance containing starch for 8 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

khoshid Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

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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

Esfahan 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
Other

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not 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

No - There is not a plan to make this available