

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Sep 2026

Effects of Green Tea Consumption on Blood Iron indices, Oxidative Stress and Hemojuvelin Gene expression in NAFLD Patients

Protocol summary

Summary

The aim of this study is to investigate the effects of green tea consumption on blood iron indices and the healing process in patients with nonalcoholic fatty liver Disease (reduced insulin resistance and reduced levels of oxidative stress) and its effects on expression of genes associated with iron metabolism (Hemojuvelin). The study is a randomized double blind, placebo controlled clinical trial. Allocation is performed by block randomization method. Based on the allocation list, uniform drug packages are prepared and coded. Patients receive their drug package based on block randomization list. This package contains green tea or placebo tablets that look the same. Main inclusion criteria: Known case of non alcoholic fatty liver Disease diagnosis of fatty liver by ultrasound, liver biopsy or liver FibroScan. Main exclusion criteria: green tea allergic reactions or other complications, taking less than 80% of the delivered dose of green tea, and being a pregnant or breast feeding. The sample size is 50. The patients in the intervention group will receive green tea extract (ECGC 450 mg/d) for 3 months and those in the control group will receive placebo for the same duration. The main outcomes include measured changes in serum iron, insulin resistance, levels of oxidative stress, and changes in Hemojuvelin gene expression.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201404132365N8**

Registration date: **2014-05-17, 1393/02/27**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-05-17, 1393/02/27

Registrant information

Name

Mohammad Reza Vafa

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8670 4734

Email address

vafa.m@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2014-05-22, 1393/03/01

Expected recruitment end date

2014-09-21, 1393/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Green Tea Consumption on Blood Iron indices, Oxidative Stress and Hemojuvelin Gene expression in NAFLD Patients

Public title

Effects of Green Tea Consumption on NAFLD

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Known case of NAFLD, diagnosed by ultrasound of the liver, liver biopsy or liver Fibroscan;

age 18 years or older; willingness to participate in research. Lack of inclusion criteria: iron deficiency anemia (hemoglobin less than 12 for women and 13 for men); allergy to green tea; alcohol consumption more than 20 g daily; viral hepatitis B and C; autoimmune hepatitis; celiac; wilson; alpha- antitrypsin deficiency. Exclusion criteria: symptoms of allergy or adverse effects of green tea consumption; taking less than 80% of the delivered dose of green tea; pregnancy or lactation; unwillingness to continue the study.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

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**

Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Hemmat Express way

City

Tehran

Postal code**Approval date**

2014-04-08, 1393/01/19

Ethics committee reference number

92-02-27-23599-100372

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

Nonalcoholic fatty liver disease (NAFLD)

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) live, not elsewhere classified

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

Hemojuvelin gene expression

Timepoint

Before and after intervention

Method of measurement

Polymerase chain reaction (PCR)

2**Description**

Blood iron indices

Timepoint

Before and after intervention

Method of measurement

Laboratory

3**Description**

Insulin resistance

Timepoint

Before and after intervention

Method of measurement

HOMA Index

4**Description**

Total antioxidant capacity

Timepoint

Before and after intervention

Method of measurement

Laboratory

Secondary outcomes**1****Description**

Fasting blood sugar

Timepoint

Before and after intervention

Method of measurement

Laboratory

2**Description**

Liver enzymes

Timepoint

Before and after intervention

Method of measurement

Laboratory

3

Description

Serum insulin

Timepoint

Before and after intervention

Method of measurement

Laboratory

4

Description

Body mass index

Timepoint

Before and after intervention

Method of measurement

Body mass index

Intervention groups

1

Description

Intervention group: green tea catechins (ECGC) 450 mg/d for three months

Category

Treatment - Drugs

2

Description

Control group: placebo for three months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Hepatitis Center

Full name of responsible person

Street address

City

Tehran

2

Recruitment center

Name of recruitment center

Research Institute for Islamic and Complementary Medicine

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences, Deputy for Research

Full name of responsible person

Seyed Ali Javad Mousavi

Street address

Iran University of Medical Sciences, Hemmat Express way

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran University of Medical Sciences, Deputy for Research

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

Iran University of Medical Sciences

Full name of responsible person

Mohammad Reza Vafa

Position

Associate Professor

Other areas of specialty/work

Street address

Iran University of Medical Sciences, Hemmat Express way

City

Tehran

Postal code

Phone

+98 21 8670 4734

Fax

Email

mrvafo@tums.ac.ir; vafa.m@iums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Mohammad Reza Vafa

Position

Associate Professor

Other areas of specialty/work

Street address

Iran University of Medical Sciences, Hemmat Express way

City

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Phone

+98 21 8670 4734

Fax

Email

mrvafo@tums.ac.ir; vafa.m@iums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

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Mohammad Reza Vafa

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Web page address

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