

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

The effect of weight loss diet with and without Hydroxy citric Acid supplement derived from Garcinia Cambogia on the serum hepcidin level and liver function in women with NAFLD: A randomized controlled clinical trial

Protocol summary

Study aim

The aim of the present study is to investigate the effects of a weight loss diet with or without Hydroxy citric acid supplementation on hepcidin level of serum and liver enzymes and sonographic image in obese women with Non Alcoholic Fatty Liver Disease .

Design

Single-blind randomized clinical trial

Settings and conduct

The study will be conducted in the Sheikh Alrais clinic of Tabriz University of Medical Sciences, and supplementation duration will be 8 weeks. Patients will be blinded to the supplement they will receive.

Participants/Inclusion and exclusion criteria

40 patients with non alcoholic fatty liver disease and BMI of 30-40 Kg/m2 will be included in the study. Pregnancy, lactation, and co-morbidity of other metabolic or anemia or thalassemia are among the exclusion criteria of the study.

Intervention groups

The subjects in both groups will receive a weight loss diet considering their dietary habits. Patients in the intervention group will get 6 HCA tablets (2 tablets before breakfast, lunch, dinner).

Main outcome variables

Serum level of hepcidin, leptin, adiponectin, interleukin1-B, interleukin6, tumor necrosis a, ferritin, hemoglobin glycosilated A1C; Liver enzymes; Lipid profile, hs-crp; FBS; fasting insulin, sonographic image;

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT201503273320N11**

Registration date: **2015-07-27, 1394/05/05**

Registration timing: **prospective**

Last update: **2018-05-05, 1397/02/15**

Update count: **1**

Registration date

2015-07-27, 1394/05/05

Registrant information

Name

Mehrangiz Ebrahimi mamagani

Name of organization / entity

Health & Nutrition faculty of Tabriz university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1335 1113

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ebrahimimamagani@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Tabriz University of Medical Sciences,

Expected recruitment start date

2015-08-01, 1394/05/10

Expected recruitment end date

2015-12-01, 1394/09/10

Actual recruitment start date

2015-08-01, 1394/05/10

Actual recruitment end date

2015-12-01, 1394/09/10

Trial completion date

empty

Scientific title

The effect of weight loss diet with and without Hydroxy citric Acid supplement derived from Garcinia Cambogia on the serum hepcidin level and liver function in women with NAFLD: A randomized controlled clinical trial

Public title

The effect of Hydroxy citric acid on non alcoholic fatty liver disease

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

non-menopausal women with Non Alcoholic Fatty Liver Diseases 18-50 years BMI=27/5-40 kg/m2 moderate activity level

Exclusion criteria:

pregnancy or lactation alcohol consumption smoking anemia or thalassemia other metabolic disorders

Age

From **18 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

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

Sample size

Target sample size: **40**

Actual sample size reached: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

From among the patients who volunteer to participate in the study, 40 individuals will be selected by 4-blocks were randomly divided in 2 groups (intervention and control) .

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the main investigators (including the student, and her supervisor and adviser professors) as well as the patients will be blinded to the type of the supplement (HCA) received by each group.

Placebo

Not 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

Golgasht street , Tabriz

City

Tariz

Province

East Azarbaijan

Postal code

5166/15731

Approval date

2015-07-06, 1394/04/15

Ethics committee reference number

TBZMED.REC.1394.324

Health conditions studied

1

Description of health condition studied

Non alcoholic fatty liver disease

ICD-10 code

K76.0

ICD-10 code description

fatty (change) of liver,not elsewhere classified

Primary outcomes

1

Description

serum level of hepcidin

Timepoint

at baseline,at the end of intervention

Method of measurement

ELIZA Kit

2

Description

liver enzymes(ALT,AST,ALP)

Timepoint

at baseline,at the end of intervention

Method of measurement

IFCC

3

Description

liver steatosis

Timepoint

at baseline,at the end of intervention

Method of measurement

liver sonography

4

Description

Added at 2017-02-13: high sensivity-C Reactive Protein

Timepoint

Added at 2017-02-13: At the baseline and at the end of intervention

Method of measurement

Added at 2017-02-13: immunoturbidometric

5

Description

Added at 2017-02-13: Fasting blood sugar

Timepoint

Added at 2017-02-13: At the baseline and at the end of intervention

Method of measurement

Added at 2017-02-13: Radioimmunoassay

6

Description

Added at 2017-02-13: Fasting insulin

Timepoint

Added at 2017-02-13: At the baseline and at the end of intervention

Method of measurement

Added at 2017-02-13: Radioimmunoassay

7

Description

Fasting ferritin

Timepoint

At the baseline and at the end of intervention

Method of measurement

ELIZA Kit

8

Description

Glycated Hemoglobin

Timepoint

At the baseline and at the end of intervention

Method of measurement

High Performance Liquid Chromatography (HPLC)

9

Description

Leptin

Timepoint

At the baseline and at the end of intervention

Method of measurement

ELIZA Kit

10

Description

Adiponectin

Timepoint

At the baseline and at the end of intervention

Method of measurement

ELIZA Kit

11

Description

Lipid profile (HDL-C, TG,TC)

Timepoint

At the baseline and at the end of intervention

Method of measurement

Enzymetic

12

Description

Interleukin-1 beta (IL-1 β)

Timepoint

At the baseline and at the end of intervention

Method of measurement

ELIZA Kit

13

Description

Interleukin- 6

Timepoint

At the baseline and at the end of intervention

Method of measurement

ELIZA Kit

14

Description

Tumor Necrosis Factor (TNF-a)

Timepoint

At the baseline and at the end of intervention

Method of measurement

ELIZA Kit

Secondary outcomes

1

Description

Anthropometry

Timepoint

at baseline and at the end of intervention

Method of measurement

scale, meter, bioelectrical impedance analyzer

2

Description

energy and nutrients intake

Timepoint

at baseline and at the end of intervention

Method of measurement

24- hour dietary recall

Intervention groups

1

Description

intervention group: weight loss diet plus 6 tablets (2 tablets 30 minutes before: breakfast- lunch - dinner) for

2 months

Category

Treatment - Drugs

2

Description

control group: just get weight loss diet for 2 months

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Sheikholrais Clinic

Full name of responsible person

Dr. Mehrangiz Ebrahimimamagani

Street address

Azadi street

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Tabriz

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East Azarbaijan

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5185747731

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mohammad-Reza Rashidi

Street address

Golgasht street, Tabriz University Of Medical Sciences, No 2 central building, 3rd floor-Vice Chancellor for Research of Tabriz University of Medical Sciences

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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

Nutrition faculty, Tabriz university of medical science

Full name of responsible person

Dr. Mehrangiz Ebrahimimamagani

Position

Nutrition Phd

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz university of medical science- nutrition faculty

Full name of responsible person

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Position

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Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Nutrition faculty of Tabriz university of medical science

Full name of responsible person

Solmaz Nomi golzar

Position

student of Master science study of health science nutrition

Latest degree

Bachelor

Other areas of specialty/work

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solmaz.nomgolzari@yahoo.com

Web page address

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

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

access starting 12 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

To access the required data, the researchers can contact Ms. Solmaz Nomi Golzar: email address: solmaz.nomgolzari@yahoo.com cellphone number: 0098 9141034898

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

The applicant should provide a brief description of the aims and methods of his Meta-analysis. His request will be assessed by the researchers, and if all of them agree to the request, the requested data will be emailed to the applicant in an Excel file format. All these procedures will take no longer than 15 days.

Comments