

# 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/m<sup>2</sup> 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 glycosylated 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

###### Email address

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/m<sup>2</sup> 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 $\beta$ )

### **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

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5185747731

**Phone**

+98 41 3335 7582

**Email**

solmaz.nomgolzari@yahoo.com

**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

**Street address**

Golgasht street, Attar neyshaburi street, nutrition faculty

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ebrahimimamagani@tbzmed.ac.ir

**Web page address**

**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**

Nutrition Phd

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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**

Nutrition

**Street address**

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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