Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Nov 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, interlukin1-B, interlukin6, tumer necrosis a, ferritin,hemoglubin 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)

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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 Dieases 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 dٍvided 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-1β)
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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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

Ntrition 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

Dr. Mehrangiz Ebrahimimamagani

Position

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Person responsible for updating data

Contact

Name of organization / entity

Nutirition 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

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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

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