

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

The Effect of Turmeric and Chicory seeds separately and together on Metabolic Condition and Oxidative ,Inflammatory Indices and Fetuin-A on Non-alcoholic fatty liver disease patients(NAFLD)

Protocol summary

Summary

Object of study: Determination the effect of Turmeric and Chicory seeds separately and together on Metabolic Condition and Oxidative, Inflammatory Indices and Fetuin-A on Non-alcoholic fatty liver disease (NAFLD) patients. Study design: Random, double blind, Control with Placebo. Study population: Patients with NAFLD will be randomly divided into 4 intervention :1 : Turmeric (receive 6 tablets containing 500 mg); 2: Chicory seeds (receive 9 g powder); 3: Turmeric and Chicory seeds and 4: Placebo (receive 6 tablets) for 3 month. Inclusion criteria: Physician definitive diagnosis of NAFLD; female: 20-50 years old and male: 20-60 years old; $24.9 \leq \text{BMI} < 40$. Exclusion criteria: Alcohol intake; Gestation or Lactation or Menopause; Liver transplantation and other liver diseases and chronic or acute liver disease (Hepatitis A,B, ...); Biliary Stone; Kidney Stone; Cancers; Inheritance diseases; Using drugs like hepatotoxic drugs; Anticoagulant drugs; Vitamin. Sample size: 84 patients (21 patients in 4 groups). Study interventions: 1-Turmeric; 2- Chicory seeds; 3-Turmeric and Chicory seeds and 4-placebo. Intervention duration: 90 days. Primary outcome: The effect of supplements on FBS, Lipid profile, Liver enzymes, Metabolic Condition and Oxidative ,Inflammatory Indices and Fetuin-A. Secondary outcome: The effect of supplements on anthropometry status, Energy and Nutrient intake.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201406183664N12**
Registration date: **2015-01-18, 1393/10/28**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-01-18, 1393/10/28

Registrant information

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Name of organization / entity

Tabriz University Of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Tabriz university of medical science

Expected recruitment start date

2014-12-06, 1393/09/15

Expected recruitment end date

2015-04-19, 1394/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Turmeric and Chicory seeds separately and together on Metabolic Condition and Oxidative ,Inflammatory Indices and Fetuin-A on Non-alcoholic fatty liver disease patients(NAFLD)

Public title

The Effect of Turmeric and Chicory seeds on Non-alcoholic fatty liver disease patients(NAFLD)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Liver steatosis on Sonographic image; Female: 20-50 years old and Male: 20-60 years old; $24.9 \leq \text{BMI} < 40$. Exclusion criteria: Alcohol intake; Gestation or Lactation or Menopause; Lose Weight Diet; Anemia; Very active or Athleta; Cardiovascular disease; Pulmonary disease; Gastrointestinal disease; Renal disease; Liver transplantation and other liver diseases and chronic or acute liver disease (Hepatitis A,B, ...); Biliious impairments; Biliary Stone; Kidney Stone; Autoimmune disease; Cancers; Inheritance diseases; Using drugs like hepatotoxic drugs; Anticoagulant drugs; Vitamin A E C and omega 3 supplement; and Oral Contraceptive drugs

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **84**

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

Ethics Committee of Tabriz University of Medical Scince

Street address

Golgasht Street, Nutrition Faculty, Tabriz University of Medical Sciences, East Azarbayjan

City

Tabriz

Postal code

Approval date

2014-12-02, 1393/09/11

Ethics committee reference number

93130

Health conditions studied

1

Description of health condition studied

Non alcoholic fatty liver

ICD-10 code

K 76

ICD-10 code description

Fatty liver

Primary outcomes

1

Description

Liver Enzyme (ALT,AST,ALP,GGT)

Timepoint

Beginning and end of the intervention

Method of measurement

Spectrophotometry

2

Description

Metabolic condition

Timepoint

Beginning and end of the intervention

Method of measurement

FBS, TC, TG and HDL Spectrophotometry, Insulin ELISA

3

Description

Oxidative Indicies

Timepoint

Beginning and end of the intervention

Method of measurement

TAC Spectrophotometry, MDA Thiobarbituric acid

4

Description

Inflammatory Indicies

Timepoint

Beginning and end of the intervention

Method of measurement

hs-CRP Immuno Turbidimetry, TNF α and IL-6 ELISA

5

Description

Fetuin A

Timepoint

Beginning and end of the intervention

Method of measurement

Fetuin A by ELISA

6

Description

Added at 2016-01-24: ICAM1

Timepoint

Added at 2016-01-24: end of the study

Method of measurement

Added at 2016-01-24: ELISA

Secondary outcomes

1

Description

Anthropometry

Timepoint

Beginning and end of intervention

Method of measurement

Scale and Meter

2

Description

Energy and Nutrient intake

Timepoint

Beginning, sixth week and end of the intervention

Method of measurement

Dietary record

Intervention groups

1

Description

Intervention Group: 500 mg Turmeric, 6 tablets/day for 12 weeks

Category

Treatment - Drugs

2

Description

Intervention Group: 9 g/ day Chicory seeds for 12 weeks

Category

Treatment - Drugs

3

Description

Intervention Group: 500 mg Turmeric(6 tablets/day) and (9 g/day) Chicory seeds for 12 weeks

Category

Treatment - Drugs

4

Description

Placebo groups: Placebo,6 tablets/day for12 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Sheykholrais and Azadi Clinic

Full name of responsible person

Aida Ghaffari

Street address

Azadi Street,Sheykholrais and Azadi Clinic,Tabriz

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research of Tabriz University of Medical Sciences

Full name of responsible person

Dr. Raf raf

Street address

Golgasht Street, Attar Neyshabori Street,Tabriz University of Medical Sciences

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research of Tabriz University of Medical Sciences

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

Nutrition Faculty, Tabriz University of Medical Sciences

Full name of responsible person

Aida Ghaffari

Position

Ph.D Candidate of Nutrition Sciences

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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