

# 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

###### Name

Maryam Rafrat

###### Name of organization / entity

Tabriz University Of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 1335 7580

###### Email address

rafratm@tbzmed.ac.ir

##### 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 Science

##### 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 $\alpha$  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

##### Other areas of specialty/work

##### Street address

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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Nutrition Faculty, Tabriz University of Medical

Sciences

### Full name of responsible person

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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*