

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effects of hydroalcohol nettle extract on glucose, lipid profile and oxidative stress in type 2 diabetic patients

#### Protocol summary

##### Summary

The purpose of this study is to investigate the effect of nettle extract supplementation on blood sugar, lipid profile and oxidative stress status in type 2 diabetic patients in a single-blind clinical trial design. 50 male and female diabetic patients divided into two 25 groups, intervention group that ingest 100mg/kg of nettle extract 3 time a day and control group that ingest placebo in same way. Patients ingest extract and placebo for 60 days and patients will not know that take extract or placebo. Food frequency questionnaire from subjects will be determined first of study and clinical assessment, physical Activity questionnaire and 24 hour recall will be determined one time in first and another time in the end of study. 5 ml venous blood sample will took from subjects after 12-14 hour fasting in sedentary status and Fasting blood sugar, total Cholesterol, HDL-cholesterol, LDL-cholesterol, Triglyceride, Insulin sensitivity, Insulin resistance, Superoxidase dysmutase, Malondyaldehyde, Glutation peroxidase and Total antioxidant capacity will be determined by laboratory methods in the first and the end of 60 days. Results will be analyzed by SPSS 15 software.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201101235670N1**  
Registration date: **2011-02-24, 1389/12/05**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2011-02-24, 1389/12/05

##### Registrant information

##### Name

Ali Tarighat-Esfanjani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 914 300 5895

##### Email address

tarighata@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

##### Expected recruitment start date

2009-10-22, 1388/07/30

##### Expected recruitment end date

2009-11-22, 1388/09/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effects of hydroalcohol nettle extract on glucose, lipid profile and oxidative stress in type 2 diabetic patients

##### Public title

Herbal therapy in diabetes

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Fasting blood sugar more than 126 mg/dl and less than 300 mg/dl; Taking usual diabetes medicines like Glibenclamide and Metformin; Age 30-50 years in both sex; BMI less than 35 Kg/m2 Exclusion criteria: Illness background(cardiovascular, kidney, GI, inflectional, liver, Thyroids, allergies, etc); Use NSAIDs,

Aspirin, Warfarin, and diuretic drugs; Smoking and use of alcohol, Herbal supplements, diet supplements, Vitamin supplements, Insulin, Anti blood pressure drugs and lipid reducer drugs; Pregnancy and Lactating; Serum Triglyceride more than 400 mg/dl; Do not use of nettle extract more than 3 days.

#### **Age**

From **30 years** old to **50 years** old

#### **Gender**

Both

#### **Phase**

2-3

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **50**

#### **Randomization (investigator's opinion)**

N/A

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Single 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 Vice chancellor for research,  
Tabriz University of Medical Science

##### **Street address**

Tabriz University of Medical Science, Golgasht Street,  
Tabriz

##### **City**

Tabriz

##### **Postal code**

#### **Approval date**

2010-10-09, 1389/07/17

#### **Ethics committee reference number**

8943

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

Diabetes

#### **ICD-10 code**

E11

#### **ICD-10 code description**

Non-insulin-dependent diabetes mellitus

## **Primary outcomes**

### **1**

#### **Description**

Glycosylated hemoglobin (HbA1c)

#### **Timepoint**

2 months

#### **Method of measurement**

Radioimmunoassay method

### **2**

#### **Description**

Fasting Blood Sugar

#### **Timepoint**

2 months

#### **Method of measurement**

Glucose oxidase method

### **3**

#### **Description**

Total Cholesterol

#### **Timepoint**

2 months

#### **Method of measurement**

Enzymatic

### **4**

#### **Description**

Triglyceride

#### **Timepoint**

2 months

#### **Method of measurement**

Enzymatic

### **5**

#### **Description**

HDL-cholesterol

#### **Timepoint**

2 months

#### **Method of measurement**

Enzymatic

### **6**

#### **Description**

LDL-cholesterol

#### **Timepoint**

2 months

#### **Method of measurement**

Friedewald equation

### **7**

#### **Description**

Insulin

#### **Timepoint**

2 months

#### **Method of measurement**

ELISA method

## Secondary outcomes

### 1

#### Description

Insulin resistance

#### Timepoint

2 months

#### Method of measurement

Matus Equation

### 2

#### Description

Malondyaldehyde

#### Timepoint

2 months

#### Method of measurement

Fluorimetry

### 3

#### Description

Super Oxidase Dismutase

#### Timepoint

2 months

#### Method of measurement

Spectrophotometric

### 4

#### Description

Glutathione Peroxidase

#### Timepoint

2 months

#### Method of measurement

Spectrophotometric

### 5

#### Description

Total Antioxidant Capacity

#### Timepoint

2 months

#### Method of measurement

Fluorescence Recovery After Photo bleaching

## Intervention groups

### 1

#### Description

100mg/kg Placebo in a glass of water every 8 hours in addition to the oral synthetic antidiabetic drugs for 3 months

#### Category

Placebo

### 2

#### Description

Nettle extract at the dose of 100 mg per Kilogram of body weight every 8 hours in addition to the oral synthetic antidiabetic drugs for 3 months

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Tabriz Sina Hospital

##### Full name of responsible person

Dr. Bahrami

##### Street address

Maralan Joint, Tabriz, Sina Hospital

##### City

Tabriz

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research, Tabriz University of Medical Sciences

##### Full name of responsible person

Dr. Alireza Ostad Rahimi

##### Street address

Tabriz University of Medical Science, Golgasht street, Tabriz

##### 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, Tabriz University of Medical Sciences

#### Proportion provided by this source

#### 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*

### 2

#### Sponsor

##### Name of organization / entity

Nutritional Research center, Tabriz University of

Medical Sciences

**Full name of responsible person**

Eng. Ghayour

**Street address**

Faculty of Health & Nutrition, Attar Street, Golgasht street, Tabriz

**City**

Tabriz

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Nutritional Research center, Tabriz University of Medical Sciences

**Proportion provided by this source**

**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**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Tabriz University of Medical Science

**Full name of responsible person**

Nazli Namazi

**Position**

MSc student of nutrition

**Other areas of specialty/work**

**Street address**

Faculty of Health & Nutrition, Attar Street, Golgasht Street, Tabriz

**City**

Tabriz

**Postal code**

**Phone**

+98 41 1335 7580

**Fax**

**Email**

nazli.namazi@yahoo.com

**Web page address**

**Person responsible for updating data**

**Contact**

**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*