Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effects of hydroalcohal 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)

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+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 hydroalcohal 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
Matius Equation

2

Description
Malondyaldehide
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

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

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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