

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

the effect of Hydroalcoholic aerial parts of *Utrica dioica* extract on Glucose level and AMPK enzyme 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 and AMPK enzyme level in type 2 diabetic patients in a single-blind clinical trial design. 60 male and female diabetic patients divided into two 30 groups. Inclusion criteria: Fasting blood sugar between 110- 200 mg/dl; Taking usual diabetes medicines that do not have effect on AMPK enzyme level like metformin and thiazolidinediones. Exclusion criteria: Illness background kidney; cardiovascular; liver. Taking usual diabetes medicines that have effect on AMPK enzyme level like metformin and thiazolidinediones; Pregnancy and Lactating; insulin injection; Smoking and use of alcohol; change in diet and exercise. Intervention group (Taking usual diabetes medicines that do not have effect on AMPK level) ingest 20mg/kg of nettle extract 3 times a day and control group that ingest placebo in same way. Patients ingest extract and placebo for 8 weeks. Before and after the study, the blood glucose, HbA1c, AMPK enzyme level and insulin levels in the drug group and the placebo group will be determined by laboratory methods in the first and the end of study. Results will be analyzed by SPSS software.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014100119364N1**
Registration date: **2015-02-15, 1393/11/26**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-02-15, 1393/11/26

Registrant information

Name

Bahare Korani

Name of organization / entity

Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 3219 2033

Email address

h.parsian@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Babol University of Medical Sciences

Expected recruitment start date

2014-12-06, 1393/09/15

Expected recruitment end date

2015-11-23, 1394/09/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

the effect of Hydroalcoholic aerial parts of *Utrica dioica* extract on Glucose level and AMPK enzyme in type 2 diabetic patients

Public title

The effect of *Utrica dioica* extract on Glucose level and AMPK (Adenosine Monophosphate Activated Protein Kinase) enzyme

Purpose

Basic science

Inclusion/Exclusion criteria

Inclusion criteria: Fasting blood sugar between 110- 200

mg/dl; Taking usual diabetes medicines that donot have effect on AMPK enzyme level like metformin and thiazolidinediones; Exclusion criteria:Illness background kidney; cardiovascular; liver. Taking usual diabetes medicines that have effect on AMPK enzyame level like metformin and thiazolidinediones; Pregnancy and Lactating; insulin injection; Smoking and use of alcohol; change in diet and exercise.

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features

Secondary Ids**1****Registry name**

-

Secondary trial Id

-

Registration date

empty

2**Registry name**

-

Secondary trial Id

-

Registration date

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of babol University of Medical Sciences

Street address

Babol University of Medical Sciences, Gang Afrooz

Ave, Babol, Mazandaran

City

Babol

Postal code

41367

Approval date

2014-12-10, 1393/09/19

Ethics committee reference number

304930

Health conditions studied**1****Description of health condition studied**

type 2 diabet

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus type 2

Primary outcomes**1****Description**

AMPK (Adenosine Monophosphate Activated Protein Kinaseenzme level

Timepoint

Befor & after intervention

Method of measurement

Immune assay

2**Description**

Glucose blood level

Timepoint

befor & after intervention

Method of measurement

spectrophotometric assay(kit)

Secondary outcomes**1****Description**

Hb A1C

Timepoint

Before & after intervention

Method of measurement

Spectrophotometric assay (kit)

2**Description**

Insulin

Timepoint

Before & after intervention

Method of measurement

Immune assay

Intervention groups

1

Description

Intervention:drug (HydroAlcoholic Utrica dioica Extract)
Intervention group (Taking usual diabetes medicines that donot have effect on AMPK level) ingest 20mg/kg of nettle extract 3 time a day for 8 weeks.

Category

Treatment - Drugs

2

Description

Control:placebo Control group(Taking usual diabetes medicines that donot have effect on AMPK level) ingest 20mg/kg of placebo 3 times a day for 8 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Rohani Hospital

Full name of responsible person

Dr. Ali Mirzapour

Street address

Rohani Hospital, Gang Afrooz Ave, Babol, Mazandaran

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research,Babol University of Medical Sciences

Full name of responsible person

Dr.Aliakbar Moghadamnia

Street address

Babol University of Medical Sciences, Gang Afrooz Ave, Babol, Mazandaran

City

Babol

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,Babol 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

Giah Essence Phytopharm co.

Full name of responsible person

Dr. Mohammad Hadi Soleimani

Street address

Dr. Soleimani pharmacy,5 Azar Blvd, Gorgan, Golestan.

City

Gorgan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Giah Essence Phytopharm co.

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

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Bahare Korani

Position

M.Sc student of clinical biochemistry

Other areas of specialty/work

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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