# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 2026

## the effect ofHydroalcholic 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 between110- 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. Intervention group (Taking usual diabetes medicines that donot have effect on AMPK level) ingest 20mg/kg of nettle extract 3 time a day and control group that ingest placebo in same way. Patients ingest extract and placebo for 8 weeks. Befor and after the study, the blood glucose، HbA1c، AMPK enzyame level and insulin evels 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)

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+98 11 3219 2033

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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 ofHydroalcholic 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 scienece

**Inclusion/Exclusion criteria**

Inclusion criteria: Fasting blood sugar between110- 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**
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## 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 (HydroAlcholic 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**
Babol

## 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**
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Babol University of Medical Sciences
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M.Sc student of clinical biochemistry
**Other areas of specialty/work**
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**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*