

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Evaluation of the *Urtica Dioica* effect on blood glucose parameters and lipid profile in patients with type 2 diabetes: a randomized double-blind clinical trial

#### Protocol summary

##### Study aim

The effect of nettle plant on blood glucose parameters and lipid profiles of patients with type 2 diabetes: a double-blind clinical trial

##### Design

A clinical trial with a control group, with a parallel group, random block and double-blind, will be conducted on 106 patients, each group consisting of 53 people. In order to randomly assign people to two groups and ensure the balance of the number of people in the groups, the block randomization method will be used. In this study, blocks with sizes of four will be created and randomly half of The people of each block will be placed in one group and half in another group SPSS 23 software will be used for data analysis.

##### Settings and conduct

Patients with type 2 diabetes will be from the clinics affiliated to the Endocrine and Metabolism Research Institute of Tehran University. The study sample will be allocated randomly and by random block method to two groups: 1- receiving the medicine 2- receiving placebo and study conducts for three months. The trial group receive 25 mg medicine every 12 hours

##### Participants/Inclusion and exclusion criteria

Inclusion: having type 2 diabetes, taking oral hypoglycemic drugs, aged 30 to 65 years Failure to enter: having type 1 diabetes, in case of insulin therapy during the last three months, and other specific types of diabetes

##### Intervention groups

The criteria of response to treatment, including fasting and two-hour blood sugar reduction, will be evaluated in both the intervention and placebo groups. By following up the condition of the patients for 3 months after the start of the treatment, the improvement in the control of blood sugar levels in the patients between the two intervention and placebo groups will be evaluated.

##### Main outcome variables

FBS BP HbA1C level Anthropoid metric criteria Kidney function Liver function Inflammatory factors Serum insulin

#### General information

##### Reason for update

Correction of information related to sampling time

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230313057707N1**  
Registration date: **2023-05-04, 1402/02/14**  
Registration timing: **prospective**

Last update: **2023-07-19, 1402/04/28**

Update count: **1**

##### Registration date

2023-05-04, 1402/02/14

##### Registrant information

###### Name

mohammad pazhouhi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 6694 4081

###### Email address

khosravi@kianpharmed.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-07-23, 1402/05/01

##### Expected recruitment end date

2024-01-21, 1402/11/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluation of the Urtica Dioica effect on blood glucose parameters and lipidprofile in patients with type 2 diabetes: a randomized double-blind clinical trial

**Public title**

"Effect of Nettles in treatment of diabetes"

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Having diabetes type 2

**Exclusion criteria:**

Allergy

**Age**

From **30 years** old to **65 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider

**Sample size**

Target sample size: **106**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In order to randomly assign people to two groups and ensure the balance of the number of people in the groups, the block randomization method will be used. In this study, blocks with sizes of four will be created and randomly half of The people of each block will be placed in one group and half in another group It is possible that half of the people will be assigned to group A (drug receiving group) and the other half will be assigned to group B (control group): 1-BAAB-6 ABBA-5 BABA-4 ABAB-3 BBAA-2 AABB Then, one of the numbers 1 to 6 will be assigned to each of the blocks of 4, and from blocks 1 to 6, simple random combinations (blocks) are made using the table of random numbers. Selection of blocks will continue until the division of 106 patients into two groups of 53 intervention and control. The selected blocks are written in a consecutive sequence and according to this sequence, the people included in the study will be assigned to one of two groups A or B. First sequence The results obtained are recorded using the block randomization method and a number from 1 to 106 will be assigned to each of the letters A and B in the created sequence, which indicates receiving the drug. Due to the unpredictability of the sequence created by the block randomization method, all researchers except the main researcher will remain unaware of the size and order of the blocks.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Conducting this research is such that neither patients nor clinical caregivers know information that may affect the results. After giving the patient's number, the clinical caregivers deliver the package prepared for his number to the patient without knowing its content, and the patient does not know whether the delivered package is a medicine or a placebo. The packages have already been prepared by the researcher. and numbered.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Research Ethics Committees of Endocrine & Metabolism Research Institute - Tehran University of Medic

**Street address**

Tehran University of Medical Sciences Headquarters, Qods Corner, Keshavarz Blvd

**City**

Tehran

**Province**

Tehran

**Postal code**

1417653761

**Approval date**

2022-04-10, 1401/01/21

**Ethics committee reference number**

IR.TUMS.EMRI.REC.1401.001

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

Type 2 Diabetes

**ICD-10 code**

E11

**ICD-10 code description**

Type 2 diabetes mellitus

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

The percentage of people who have a fasting blood sugar level above 120 mg/dl

## **Timepoint**

Blood test before starting the drug and three months later (after taking the drug completely)

## **Method of measurement**

Fasting blood sugar test

## **Secondary outcomes**

### **1**

#### **Description**

HbA1C

#### **Timepoint**

Blood test before starting the drug and three months later (after taking the drug completely)

#### **Method of measurement**

HbA1C test

### **2**

#### **Description**

Creatinine

#### **Timepoint**

Blood test before starting the drug and three months later (after taking the drug completely)

#### **Method of measurement**

Creatinine test

### **3**

#### **Description**

Fasting insulin

#### **Timepoint**

Blood test before starting the drug and three months later (after taking the drug completely)

#### **Method of measurement**

Fasting insulin test

### **4**

#### **Description**

Cholesterol

#### **Timepoint**

Blood test before starting the drug and three months later (after taking the drug completely)

#### **Method of measurement**

Cholesterol test

### **5**

#### **Description**

Triglyceride

#### **Timepoint**

Blood test before starting the drug and three months later (after taking the drug completely)

#### **Method of measurement**

Triglyceride test

## **Intervention groups**

### **1**

#### **Description**

Intervention group: The nettle group will receive 2 capsules of 250 mg, which will contain 25 mg of the active substance of nettle along with fillers, every 12 hours for 3 months. The status of medication use will be followed up by the researcher once a week through a phone call. A contact number will be provided to the patients to contact the researcher in case of any complications or other problems. In case of complications such as hypoglycemia or ketoacidosis, the drugs will be stopped and the patient will be evaluated and treated if necessary and excluded from the study. People will be told to bring the envelopes containing the drugs with them in any case (whether in case of complete use or in case of incomplete use) in the face-to-face examination at the end of the clinical trial for each patient. Clinical trials of patients up to 3 months after The start of treatment is monitored. The results of the tests are recorded in the questionnaire.

#### **Category**

Treatment - Drugs

### **2**

#### **Description**

Control group: The placebo group will receive 2 capsules similar to nettle capsules that only contain fillers every 12 hours for 3 months. The status of medication use will be followed up by the researcher once a week through a phone call. A contact number will be provided to the patients to contact the researcher in case of any complications or other problems. In case of complications such as hypoglycemia or ketoacidosis, the drugs will be stopped and the patient will be evaluated and treated if necessary and excluded from the study. People will be told to bring the envelopes containing the drugs with them in any case (whether in case of complete use or in case of incomplete use) in the face-to-face examination at the end of the clinical trial for each patient. Clinical trials of patients up to 3 months after The start of treatment is monitored. The results of the tests are recorded in the questionnaire.

#### **Category**

Placebo

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Endocrine & metabolism research institute-tehran university

##### **Full name of responsible person**

Mohammad Pazhouhi

##### **Street address**

Flat No. 3, 2nd floor, No. 8, Hamedan St., North Kargar Ave., Tehran., Iran

##### **City**

Tehran

##### **Province**

Tehran  
**Postal code**  
1418693884  
**Phone**  
+98 21 6694 4081  
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**Email**  
elhamfaghani69@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Kian Pharmed Parsian  
**Full name of responsible person**  
Saeed Akbarian  
**Street address**  
Flat No. 3, 2nd floor, No. 8, Hamedan St., North  
Kargar Ave., Tehran., Iran  
**City**  
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**Province**  
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1418693884  
**Phone**  
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**Fax**  
+98 21 6694 4084  
**Email**  
elhamfaghani69@yahoo.com

#### Grant name

**Grant code / Reference number**

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

Yes

#### Title of funding source

Kian Pharmed Parsian

#### Proportion provided by this source

100

#### Public or private sector

Private

#### Domestic or foreign origin

Domestic

#### Category of foreign source of funding

*empty*

#### Country of origin

#### Type of organization providing the funding

Academic

## Person responsible for general inquiries

#### Contact

**Name of organization / entity**  
Kian Pharmed Parsian  
**Full name of responsible person**  
Ali Khosravi  
**Position**  
PhD

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Medical Pharmacy

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Flat No. 3, 2nd floor, No. 8, Hamedan St., North  
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## Person responsible for scientific inquiries

#### Contact

#### Name of organization / entity

Kian Pharmed Parsian

#### Full name of responsible person

Ali Khosravi

#### Position

Assistant Professor

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Medical Pharmacy

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## Person responsible for updating data

#### Contact

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Kian pharmed parsian

#### Full name of responsible person

Ali Khosravi

#### Position

Assistant Professor

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Medical Pharmacy

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available