Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Evaluation of the Urtica Dioica effect on blood glucose parameters and lipidprofile 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

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Email address

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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
Reasearch Ethics Commitees 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Saeed Akbarian
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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
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Other areas of specialty/work
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Person responsible for updating data

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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