

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 2026

### Evaluation of the Effect of pistaciakhinjuk leaves billardieri on metabolic control and quality of life in type 2 diabetic patients .

#### Protocol summary

fasting plasma glucose, mean glycosylated hemoglobin (HBA1C) and quality of life in type 2 diabetic patients.

#### Study aim

Evaluation of the Effect of pistaciakhinjuk leaves billardieri on metabolic control and quality of life in type 2 diabetic patients referred to traditional medicine clinics of Isfahan city in 2019.

#### Design

Clinical trial with control and experimental groups, with parallel groups, random selection, phase 2 on 72 patients

#### Settings and conduct

Diabetes is the most common metabolic disease in the world. It has been dubbed the "latent epidemic" by the World Health Organization. According to the International Diabetes Federation, the prevalence of diabetes in people over the age of 18 in the world in 2014 was estimated at 9% . In Iranian clinics affiliated to Isfahan University of Medical Sciences (Sedigheh Tahereh Endocrine and Metabolism Center), it is performed randomly by the experimental group using Kalkhang tea.

#### Participants/Inclusion and exclusion criteria

Type 2 diabetes and the use of oral antihypertensive drugs are approved by your doctor. No insulin injection  
Have a history of at least 2 years of diabetes  
Have an age range between 30 and 60. Have taken oral antihypertensive drugs at least three months ago. The patient's body mass index should be less than 30. : The woman is pregnant. Be breastfeeding over time. HBA1C hemoglobin in the last three months of the patient is 6.5% \_ 5.5%

#### Intervention groups

The experimental group consumes 5 grams of kale leaf every 24 hours for 1 month and the control group proceeds according to their usual treatment. The average fasting blood sugar test at the beginning of the study, 1 month and a month later, as well as the percentage of hemoglobin A1C at the beginning of the study and 3 months after all, will be taken.

#### Main outcome variables

Determination and comparison of kohlrabi on mean

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210801052040N1**

Registration date: **2021-08-08, 1400/05/17**

Registration timing: **retrospective**

Last update: **2021-08-08, 1400/05/17**

Update count: **0**

##### Registration date

2021-08-08, 1400/05/17

##### Registrant information

##### Name

kobra afzali

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3792 7533

##### Email address

kosarafzali96@mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-12-22, 1398/10/01

##### Expected recruitment end date

2020-03-29, 1399/01/10

##### Actual recruitment start date

2021-02-28, 1399/12/10

##### Actual recruitment end date

2021-05-31, 1400/03/10

**Trial completion date**

2021-06-20, 1400/03/30

**Scientific title**

Evaluation of the Effect of pistaciakhinjuk leaves billardieri on metabolic control and quality of life in type 2 diabetic patients .

**Public title**

Evaluation of the Effect of pistaciakhinjuk leaves billardieri on metabolic control and quality of life.

**Purpose**

Treatment

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

Having type 2 diabetes and taking oral hypoglycemic drugs No insulin injection Have a history of at least 2 years of diabetes Have an age range between 30 and 60 Have taken oral antihypertensive drugs at least three months ago. The patient's body mass index should be less than 30. Willing to participate in research.

**Exclusion criteria:**

The woman is pregnant. During lactation. Hemoglobin HBA1C in the last three months is 6.5% - 5.5%.

**Age**

From **30 years** old to **60 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **72**

Actual sample size reached: **72**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

This study is a clinical trial in an easy and accessible method, then in the form of random block allocation, which is the most practical method of quadruple blocks in the blocking method. In this trial, the intervention group is group A and the control group is group B. In each block, waiting We have to be AABB. In this block layout, the combination of blocks as 1. AABB 2. ABAB 3. ABBA 4. BBAA 5. BABA 6, BAAB is divided. To make randomization completely unpredictable. Moving in a random number table should be from top to bottom, from left to right or right to left. According to these 6 blocking modes, we refer to the table of random numbers. For example, in the table of random numbers, the first block is AABB, which according to the table of random numbers is 1. AABB 1321. In this way, the number 1 of the intervention, the number 3 of the intervention, the number 2 of the control, the number 9 are deleted because the block modes are 6, then the number 1 is the control group and so on the other 9 blocks according to the random number table. We go and the samples are selected. From each of the studied groups and from the patients referring to the Iranian medicine clinics of the hospitals affiliated to Isfahan University of Medical Sciences who have the inclusion

criteria, which will be done by block random allocation method in 2 control and test groups. we put. The experimental group takes herbal medicines under the supervision of a traditional medicine specialist and the dose of chemical medicines is adjusted by the doctor. The control group is taking oral medication under the supervision of a physician.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

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

empty

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

Ethics Committee of Isfahan University of Medical Sciences

**Street address**

Hezar Jerib St., Isfahan University of Medical Sciences and Health Services, Central Headquarters

**City**

Esfahan

**Province**

Isfahan

**Postal code**

031-3668-0048

**Approval date**

2020-06-10, 1399/03/21

**Ethics committee reference number**

IR.MUI.RESERCH.REC.1399.136

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

Type 2 diabetes

**ICD-10 code****ICD-10 code description**

Type 2 diabetes,

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

Metabolic control indicators and quality of life

**Timepoint**

Fasting blood sugar before the intervention, 1 month and 3 months later; Hemoglobin (A1C) before intervention and 3 months after

**Method of measurement**

Lancet glucometer, Jacobson Diabetes Quality Of Life

**Secondary outcomes**

empty

**Intervention groups**

1

**Description**

Intervention group: Kalkhang leaf tea, 120 cc of 5 grams  
Kalkhang leaf tea 2 times in 24 hours (after breakfast  
and dinner) for 1 month.

**Category**

Treatment - Drugs

**Recruitment centers**

1

**Recruitment center****Name of recruitment center**

Sedigheh Tahereh Endocrinology and Metabolism  
Center, Isfahan

**Full name of responsible person**

Sasan Haghghi

**Street address**

Isfahan - Jomhory Square - Khorram St. - after the  
intersection of martyrs - Hazrat Sedigheh Tahereh  
Educational, Therapeutic and Research Complex -  
Ground Floor - Endocrine and Metabolism Research  
Center

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Esfahan

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81876-98191

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+98 31 3335 9933

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emrc@mui.ac.ir

**Sponsors / Funding sources**

1

**Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Fakhri Saboohi

**Street address**

Isfahan University of Medical Sciences,Isfahan,Iran

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sabohi@nm.mui.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Esfahan University of Medical Sciences

**Proportion provided by this source**

80

**Public or private sector**

Public

**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**

Esfahan University of Medical Sciences

**Full name of responsible person**

Fakhri Saboohi

**Position**

the coach

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

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**Position**

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Master

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Esfahan University of Medical Sciences  
**Full name of responsible person**  
kobra afzali  
**Position**  
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kosarafzali96@mui.ac.ir

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

### Justification/reason for indecision/not sharing IPD

There is no more information

### Study Protocol

No - There is not a plan to make this available

### Statistical Analysis Plan

No - There is not a plan to make this available

### Informed Consent Form

No - There is not a plan to make this available

### Clinical Study Report

No - There is not a plan to make this available

### Analytic Code

No - There is not a plan to make this available

### Data Dictionary

No - There is not a plan to make this available