

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)

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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
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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Fakhri Saboohi

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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

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 updating data

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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