

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

Preparation and comparison of anti-diabetic effects of palm kernel powder plates with placebo in diabetic patients treated with metformin

Protocol summary

Study aim

Preparation and evaluation of anti-diabetic effects of palm kernel powder pellets in reducing blood sugar in type 2 diabetic patients

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 on 140 patients. We use a simple randomization model using a table of random numbers (computer randomization method).

Settings and conduct

This study is a double-blind clinical trial study that will be performed on type 2 diabetic patients referred to the diabetes clinic. 140 patients will be randomly divided into intervention and control groups (70 people in each group). In addition to metformin, the patient will receive the drug (date kernel plate or placebo) in sealed packets that are encoded. Coded by one of the design partners and the doctor, the evaluator, and the patient are blind

Participants/Inclusion and exclusion criteria

Inclusion criteria for patients aged 30 to 60 years with type 2 diabetes and At least 6 months have passed since the diagnosis of diabetes Exclusion criteria: 1. During the study, he gets another disease and receives another medicine 2. Getting pregnant while studying 3. Lack of adherence to the treatment protocol 4. Change in patients' medication regimen

Intervention groups

Intervention group: 70 patients in addition to metformin 500 mg tablets (one every 12 hours), palm kernel plate, are given one 200 mg capsule every 12 hours for 90 days and fasting blood sugar, 2-hour blood sugar daily and also in The end of the study HbA1C is analyzed control group: 70 patients in addition to metformin 500 mg tablets (one every 12 hours), placebo, are given one 200 mg capsule every 12 hours for 90 days and fasting blood sugar, 2-hour blood sugar daily and also in The end of the study HbA1C is analyzed

Main outcome variables

Fasting blood sugar level HbA1C levels 2 hour blood

sugar level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170809035599N2**

Registration date: **2021-09-04, 1400/06/13**

Registration timing: **prospective**

Last update: **2021-09-04, 1400/06/13**

Update count: **0**

Registration date

2021-09-04, 1400/06/13

Registrant information

Name

Amanollah Zarei Ahmady

Name of organization / entity

Ahvaz Jundishapur University of Medical Science

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2022-02-20, 1400/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Preparation and comparison of anti-diabetic effects of palm kernel powder plates with placebo in diabetic patients treated with metformin

Public title

Anti-diabetic Herbal Drug

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having type 2 diabetes Less than 6 months have passed since the onset of the disease Fasting blood sugar is less than 200 and HbA1C is less than 9 Age 30-60 years

Exclusion criteria:

Pregnant or lactating patient Age under 30 or over 60 years Advanced complications of diabetes Patients undergoing chemotherapy

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

Individuals are placed in two intervention or control groups using allocation Random Software (RAS) through a four- and six-block block with a 1: 1 allocation ratio. Consume one every 12 hours for 90 days. Random allocation sequences will be generated by the non-researcher, cans will be numbered from 1 to 140. Both groups will receive routine metformin treatment.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient receives the drug (date kernel plate or placebo) in sealed envelopes. The coding is done by one of the project partners and the doctor, the evaluator and the patient are blind.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ahvaz Jundishapur University of Medical Science

Street address

Golestan

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Ahvaz

Province

Khuzestan

Postal code

6135715794

Approval date

2021-06-26, 1400/04/05

Ethics committee reference number

IR.AJUMS.REC.1400.233

Health conditions studied

1

Description of health condition studied

Diabetes type2

ICD-10 code

Z79.84

ICD-10 code description

oral antidiabetic drugs

Primary outcomes

1

Description

Fasting blood sugar, HbA1C ,2-hour blood sugar

Timepoint

Measurement of fasting blood sugar, HbA1C .Blood sugar 2 hours at the beginning of the study and after 3 months

Method of measurement

Blood glucose measuring device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 70 patients in addition to metformin 500 mg tablets (one every 12 hours), palm kernel plate, are given one 200 mg capsule every 12 hours for 90 days

Category

Treatment - Drugs

2

Description

control group: 70 patients in addition to metformin 500 mg tablets (one every 12 hours), placebo are given one capsule 200 mg every 12 hours for 90 days

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Khomeini Hospital

Full name of responsible person

Amanollah Zarei Ahmady

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24 meter street of Imam Khomeini Hospital, endocrinology clinic

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

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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

Ahvaz University of Medical Sciences

Proportion provided by this source

100

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**

Ahvaz University of Medical Sciences

Full name of responsible person

Zahra Farhangian

Position

Assistant professor

Latest degree

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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