Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jul 2026

Investigating the effect of consumption of walnut inner shell on blood sugar and lipid profile of patients with diabetes in Sanandaj

Protocol summary

Study aim
Determining the effect of walnut inner shell consumption on blood sugar and lipid profile of patients with diabetes in Sanandaj

Design
The present clinical trial has a control group, randomized, phase 2 on 72 patients. Blocking will be used for randomization and stsa software will be used for data analysis.

Settings and conduct
The present study is a randomized controlled clinical trial study that will be performed among patients with diabetes in clinics and various care centers in Sanandaj.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age over 18 years, patient with type 2 diabetes and at least 3 months have passed since their diabetes was confirmed Exclusion criteria: severe physical condition, chronic heart, kidney and liver failure

Intervention groups
1- Intervention group: includes patients with type 2 diabetes who will take oral walnut shell capsule once a day for 3 months at the same time as taking oral anti-diabetic drugs. 2- Control group: Patients with type 2 diabetes who will take only oral anti-diabetic drugs

Main outcome variables
Blood sugar: In this study, the mean blood glucose level of the patient's fasting blood before and after the intervention and is measured by a blood sample test. Lipid profile: The lipid profile in this study is the average size of lipoproteins in the time before and after the intervention. Glycosylated hemoglobin (HbA1c): A form of hemoglobin that is primarily used to measure the detection of moderate blood sugar levels over long periods of time.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20121015011122N3**
Registration date: **2021-02-08, 1399/11/20**
Registration timing: **prospective**

Last update: **2021-02-08, 1399/11/20**
Update count: **0**

Registration date
2021-02-08, 1399/11/20

Registrant information

Name
Hossein Feizi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 87 3377 2638

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h_feyzi65@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-04-08, 1400/01/19

Expected recruitment end date
2021-09-10, 1400/06/19

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of consumption of walnut inner shell on blood sugar and lipid profile of patients with diabetes in Sanandaj

Public title
the effect of consumption of walnut inner shell on blood sugar and lipid profile of patients with diabetes
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age over 18 years Patients with type 2 diabetes have been diagnosed with diabetes for at least 3 months. Patient cooperation Completion of the informed consent form for participation in the research program by the participants Do not take insulin Take at least one oral antidiabetic medicine (metformin) HbA1c≥6.5% and FBS≥126 mg / dl Lack of special diet (except diabetic diet) No chronic heart, kidney and liver failure Do not use drugs and alcohol It is good to have no mental illness and no physical condition
Exclusion criteria:
Patients taking insulin. Patients with type 1 diabetes. Patients with severe physical and mental conditions. Patients who are allergic to walnuts. Women who are pregnant or breastfeeding.
Age
From **18 years** old to **80 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **72**
Randomization (investigator's opinion)
Randomized
Randomization description
First, by referring to different medical centers in Sanandaj, the number of patients diagnosed with diabetes has been determined and this will be done until the sample size is completed. The samples are then randomly divided (using a table of random numbers) into case and control groups. Random 4-block blocking is done in the form of random blocks. If we have two groups A and B, it is as follows. The selection of 4 blocks is also done completely randomly. AABB ABAB ABBA BAAB BABA BBAA
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
Kurdistan University of Medical Sciences
Street address
in front of Shadi hotel, Pasdaran street, Sanandaj city, Kurdistan province, Iran
City
sanandaj
Province
Kurdistan
Postal code
6617774891
Approval date
2021-01-07, 1399/10/18
Ethics committee reference number
IR.MUK.REC.1399.194

Health conditions studied

1

Description of health condition studied
Pharmacological treatment
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Blood sugar: The mean blood sugar in this study is the average fasting blood sugar of the patient.
Timepoint
Before and after the intervention time
Method of measurement
Blood sample test

2

Description
Lipid profile: Lipid profile in this study is the average size of lipoproteins.
Timepoint
Before and after the intervention time
Method of measurement
Blood sample test

3

Description
Glycosylated hemoglobin (HbA1c): A form of hemoglobin that is primarily used to measure the detection of moderate blood sugar levels over long periods of time.
Timepoint
Before and after the intervention time
Method of measurement
Blood sample test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The intervention group includes patients with type 2 diabetes who will take oral walnut shell capsules once a day for 3 months at the same time as taking oral anti-diabetic drugs.
Category
Treatment - Drugs

2

Description
Control group: The control group is patients with type 2 diabetes who will take only oral anti-diabetic drugs.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Tohid Hospital
Full name of responsible person
Dr. Asad Fathipour
Street address
Tohid Hospital, Gryashan Street, Sanandaj, Kurdistan
City
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6617774891
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sanandaj University of Medical Sciences
Full name of responsible person
Dr. Farzin Rezaei
Street address
University Campus, Kurdistan University of Medical Sciences, in front of Shadi Hotel, Pasdaran St, Sanandaj, Kurdistan Province, Iran
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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
Sanandaj 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
Sanandaj University of Medical Sciences
Full name of responsible person
hossein feizi
Position
Faculty member
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
School of Nursing and Midwifery, Kurdistan University of Medical Sciences, in front of Shadi Hotel, Pasdaran St, Sanandaj, Kurdistan Province, Iran
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Latest degree
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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)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
The results of the study will be published as general data and as an article or lecture.
When the data will become available and for how long
Access period starts one month after the article is published
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
During the formal steps and with the permission of the project manager and the author in charge of the article, the documentation can be used.
From where data/document is obtainable
The main executor of the project
What processes are involved for a request to access data/document
Sending a request for cooperation with the project manager, getting a response to consent to use the documents and sending the necessary documents
Comments