

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Primary Evaluation of Anti hyperglycemic Effect of internal septum of Juglans regia in patients with diabetes mellitus type II: A Double blind Randomized Clinical Trial

Protocol summary

Study aim

Determining the effectiveness of internal septum of Juglans regia hydro-alcoholic extract on lowering blood glucose. Sub-objectives: Determining the effect of J.regia internal septum extract on weight, waist circumference, waist to hip ratio, hypoglycemia, systolic and diastolic blood pressure, insulin resistance according to QUICKI and HOMA IR index

Design

Clinical trial with control group, parallel groups, double-blind, randomized, phase 3 on 60 patients. The blocks randomization scheme of permuted method is used for randomization.

Settings and conduct

Blinding: The patient and the researcher, including resident, the first and second supervisor professors, do not know about the capsules and the randomization will be done by the third supervisor. Location: Diabetes Clinic of IKHC, Tehran Procedure: Patients are divided into 2 equal groups of 30 people. One group of drugs and another is placebo are given three times a day before meals. Lab tests (check blood levels of hemoglobin A1C, fasting plasma glucose, insulin, hs CRP, C-peptide AST, ALT and ALP, bilirubin and serum creatinine, weight, height and waist and hip circumference and blood pressure, urine analysis (for proteinuria)) Are taken at the beginning and end of the study. To ensure patients' cooperation, medications are provided once every 6 weeks.

Participants/Inclusion and exclusion criteria

Inclusion: Gain conscious satisfaction, 25-70 years, $7 \geq \text{HbA1C} \leq 9$ and $\text{FPG} = 130\text{-}250 \text{ mg / dl}$, receiving metformin and/or other anti-diabetic agents, constant diet, activity and drug regimen. Exclusion: walnut allergy, immune deficiency, pregnancy and lactation, cardiovascular disease, receiving medications that alter blood glucose, uncontrolled thyroid disease, acute

infection, DKA

Intervention groups

intervention: 3 cap of walnut internal septum daily, before meal. Control : 3 cap of placebo daily, before meal.

Main outcome variables

Hemoglobin A1C

General information

Reason for update

Sample size correction

Acronym

IRCT registration information

IRCT registration number: **IRCT20201229049877N1**

Registration date: **2021-02-06, 1399/11/18**

Registration timing: **prospective**

Last update: **2022-02-14, 1400/11/25**

Update count: **2**

Registration date

2021-02-06, 1399/11/18

Registrant information

Name

Fatemeh Afra

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4441 4751

Email address

f-afra@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-04, 1400/01/15
Expected recruitment end date
 2021-10-07, 1400/07/15
Actual recruitment start date
 2021-05-15, 1400/02/25
Actual recruitment end date
 2021-12-11, 1400/09/20
Trial completion date
 2021-12-21, 1400/09/30

Scientific title
 Primary Evaluation of Anti hyperglycemic Effect of internal septum of Juglans regia in patients with diabetes mellitus type II: A Double blind Randomized Clinical Trial

Public title
 Evaluation of Anti hyperglycemic Effect of internal septum of Juglans regia in patients with diabetes mellitus type II: A Double blind Randomized Clinical Trial

Purpose
 Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Obtain consent from patients Age between 25 and 70 year old HbA1C $\geq$ 7% and less than 9% and FPG = 130-250 mg / dl Take metformin and/or other anti-diabetic agents (in maximum and constant dose for three months) or metformin alone (in maximum and constant dose for three months) Constant diet and physical activity during the study (according to a questionnaire translated and validated into Persian) The patient's anti-diabetic medication regimen remained constant during the study No allergies to walnuts
Exclusion criteria:
 History of walnut allergy Immune system defects Pregnancy and lactation Cardiovascular disease (coronary artery ischemia, EF <45%) Take medications that change blood glucose levels (corticosteroids, tacrolimus, anti-AIDS drugs, antipsychotic drugs) Uncontrolled thyroid disease Acute infection History of diabetic ketoacidosis eGFR<60 ml/min Acute hepatitis (increase in ALT and AST to more than 10 to 20 times normal) cirrhosis Proliferative retinopathy Severe weight loss (at least 10% over 6 months) Consumption of any other medicine and herbal products, including walnuts

Age
 From **25 years** old to **70 years** old

Gender
 Both

Phase
 3

Groups that have been masked

- Participant
- Investigator

Sample size
 Target sample size: **60**
 Actual sample size reached: **60**

Randomization (investigator's opinion)
 Randomized

Randomization description
 Randomization outcome will be done in a block of 4 and

through using excel software. This randomization will as follow; at patients arrival to outpatient diabetes clinic, 4 cards (asA, B, C and D) will be introduced and the patient can be chosen only one of them, so then according to the table (four blocks), patient will be divided in group A or B. Patients will be divided into two groups of 30 people.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, both of patients and researcher are blinded. Placebo is prepared same as the drug capsule. Drug and placebo are coded into A and B by the third supervisor and randomized by block randomization method.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of the Research Institute of Pharmaceutical Sciences, Tehran University of

Street address

Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafshan & South Falamak, Qods Town, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1476947143

Approval date

2020-12-22, 1399/10/02

Ethics committee reference number

IR.TUMS.TIPS.REC.1399.133

Health conditions studied

1

Description of health condition studied

Type 2 diabetes mellitus

ICD-10 code

E11.9

ICD-10 code description

Type 2 diabetes mellitus without complications

Primary outcomes

1

Description

Decreases of hemoglobin A1C (HbA1C)c

Timepoint

0 and 12 weeks after initiation of the drug

Method of measurement

serum level measurement

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: in this group, each patient will receive a capsule containing lyophilized powder of hydroalcoholic extract of internal septum of walnut (*J. regia*) three times a day before meals for 3 months in addition to other anti-diabetic treatments. At the beginning and end of the study (End of the 12th week), 5 cc of blood samples will be taken from patients to assess blood levels of hemoglobin A1C, fasting blood glucose, insulin, hs CRP, C-peptide AST, ALT,ALP, serum bilirubin and creatinine. The patient's weight, height and waist circumference, hip circumference and blood pressure are also measured. A urine sample is taken from the patient at the beginning and end of the study for urine analysis (for assessing proteinuria).

Category

Treatment - Drugs

2

Description

Control group: in this group, each patient will receive a capsule containing pectin as placebo three times a day before meals for 3 months in addition to other anti-diabetic treatments. At the beginning and end of the study (End of the 12th week), 5 cc of blood samples will be taken from patients to assess blood levels of hemoglobin A1C, fasting blood glucose, insulin, hs CRP, C-peptide AST, ALT,ALP, serum bilirubin and creatinine. The patient's weight, height and waist circumference, hip circumference and blood pressure are also measured. A urine sample is taken from the patient at the beginning and end of the study for urine analysis (for assessing proteinuria).

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini hospital complex ,Tehran

Full name of responsible person

Fatemeh Afra

Street address

Dr .Gharib Ave

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Imamhospital@tums.ac.ir

Web page address

<http://ikhc.tums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Soha Namazi

Street address

pharmaceutical care department,Valiasr hospital,Imam Khomeini Hospital Complex, Tohid Squire

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namazisoha@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Soha Namazi

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

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Position

Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Fatemeh Afra

Position

resident

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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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

Yes - There is 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

Title and more details about the data/document

Publication of clinical report

When the data will become available and for how long

After printing the results

To whom data/document is available

All people who work in the field of health

Under which criteria data/document could be used

There are no special conditions

From where data/document is obtainable

Databases in which the article is indexed

What processes are involved for a request to access data/document

Search for keywords in databases

Comments