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≥HbA1C≤9 and FPG = 130-250 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
Fateme Afra
Name of organization / entity
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
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≥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 (as A, 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 Zarafashan & 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

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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
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
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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