Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 May 2026

To evaluate the effect of a Traditional Persian Medicine product, composed of Sweet Almond and Plantago seed, on Proteinuria in patients with Diabetic Nephropathy.

Protocol summary

Study aim

Nephropathy is albuminuria and decreased (GFR) in diabetic patients The effect of sweet almonds and plantago in proteinuria has been proved separately in scientific studies .this study is designed to investigate the role of this compound in progression and control of this complication.

Design

The clinical trial will be conducted with one intervention group and one control group, randomized blocked, sample size of 60, followed for two months.

Settings and conduct

After approving the project & registering the study on the site and obtaining the clinical trial code, the research will be conducted in Dr. Saghafi Clinic of kidney subspecialty in Shahid Beheshti Hospital in Qom. This study is a randomized clinical trial with two groups of intervention and control. Patients with diabetic nephropathy are evaluated by a renal subspecialty and according to the inclusion criteria, eligible patients will be selected from among them. After selecting a sufficient number of patients, they will be divided into the intervention group and one control group by random allocation method.

Participants/Inclusion and exclusion criteria

Entry criteria: Informed consent. Excretion of albumin between 30-300 mg in 24-hour urine.Blood pressure less than 160 mmHg.HbA1C between 7 and 9%. Exclusion criteria: Complications. Increase proteinuria.Drug allergy

Intervention groups

Patients will be randomly divided into two groups of 30 patients. The duration is two months. 1st group will be given Losartan 25 mg twice a day every 12 hours. (8am/8pm or any other time other than the time of use of traditional medicine products) 2nd group will be given Losartan 25 mg twice a day every 12 hours plus traditional medicine product (10 grams sachet) twice a day two hours after breakfast and two hours after lunch along with a little water.

Main outcome variables

Decreased or no Proteinuria in patients with Diabetic Nephropathy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221015056179N1**
Registration date: **2022-10-17, 1401/07/25**
Registration timing: **prospective**

Last update: **2022-10-17, 1401/07/25**
Update count: **0**

Registration date

2022-10-17, 1401/07/25

Registrant information

Name
Romella Haider
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 25 3294 3187
Email address
rheidar@muq.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-05, 1401/08/14

Expected recruitment end date

2023-11-05, 1402/08/14

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
To evaluate the effect of a Traditional Persian Medicine product, composed of Sweet Almond and Plantago seed, on Proteinuria in patients with Diabetic Nephropathy.

Public title
To evaluate the effect of Sweet Almond and Plantago seed, on Proteinuria in patients with Diabetic Nephropathy.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Informed consent to enter the project People aged 30 to 70 years No kidney failure or any other disease that leads to diabetic nephropathy No symptoms of urinary tract infection during study Not taking anticoagulants, corticosteroids Excretion of albumin between 30-300 mg in 24-hour urine Blood pressure less than 160 mmHg Potassium less than 5.8 mA/L GFR more than 60 ml per minute per 1.73 m3 body Creatinine less than 2 mg/dl No professional athletes Not having Chronic neurological disease (severe depression and anxiety) Non-pregnancy and lactation SGPT rate less than three times normal before study (below 100 units per liter) HbA1C between 7 and 9% No urinary tract infection and kidney ducts.
Exclusion criteria:
Causing any complications Dissatisfaction with follow-up treatment Increase proteinuria Drug allergy
Age
From **30 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Random allocation of patients to two groups is done using random block allocation method using 4 and 6 blocks. Block sequences are assigned to groups using specified software and patients are assigned to groups based on the determined sequence.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Specialized Committee on Ethics in Biomedical Research
Street address
Safashahr, Jehad Daneshgaahi, Street, Shahid Niasari Alley, No. 85
City
ghoum
Province
Ghoum
Postal code
3716986466
Approval date
2022-10-15, 1401/07/23
Ethics committee reference number
IR.MUQ.REC.1401.149

Health conditions studied

1

Description of health condition studied
Proteinuria in Diabetic Nephropathy
ICD-10 code
E13.42
ICD-10 code description
Other specified diabetes mellitus with diabetic polyneuropathy

Primary outcomes

1

Description
Decreased Proteinuria in urine
Timepoint
At the beginning of the study (before the intervention) and on days 30 after the intervention
Method of measurement
UA Urinary Protein

2

Description
Decreased Proteinuria in 24 hour Urinary protein
Timepoint
At the beginning of the study (before the intervention) and on day 60 after the intervention
Method of measurement
24 hour Urinary Protein

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:This group will be given Losartan 25 mg twice a day every 12 hours as well as traditional medicine product (10 grams sachet) twice a day two hours after breakfast and two hours after lunch along with a little water.
Category
Treatment - Drugs

2

Description
Control group: This group will be given Losartan 25 mg twice a day to be given one every 12 hours. (8am/8pm or any other time other than the time of use of traditional medicine products)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Beheshti hospital
Full name of responsible person
Romella Haider
Street address
Beheshti hospital, Beheshti Blvd, Emam khomaini Squ.
City
ghoum
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ghoum University of Medical Sciences
Full name of responsible person
Mr. Hossein Saghafi
Street address
Shahid Lavasani St. (Sahili), Qom University of Medical Sciences and Health Services
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3713649373
Phone
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rheidar@muq.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ghoum 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
Ghoum University of Medical Sciences
Full name of responsible person
Romella Haider
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Traditional Medicine
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Person responsible for scientific inquiries

Contact
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Ghoum University of Medical Sciences
Full name of responsible person

Romella Haider

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
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Person responsible for updating data

Contact

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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