Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effect of Qurs-e Tabasheer, a traditional Persian formula, on blood glucose and renal complications in patients with diabetic nephropathy, a randomized controlled trial

Protocol summary

Study aim
Determination of the effect of a traditional medicine "Qurs-e Tabasheer" on blood glucose and renal complications in patients with diabetic nephropathy

Design
A controlled, double-blind, randomized, phase 3 Clinical trial on 60 patients

Settings and conduct
Sixty patients with diabetic nephropathy referred to the dialysis ward of Imam Ali Hospital are included in the study by available sampling. This is a double blind study in which participants, clinical caregiver, researcher and outcome evaluator are blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: People over 18 years old; Patients with diabetes and diabetic nephropathy; People receiving a stable dose of ACEI(Angiotensin converting enzyme inhibitors) or ARB(Angiotensin II Receptor Blockers); Albuminuria more than 30 mg per day; eGFR between 15 and 30 (stage 4 CKD) Exclusion criteria: Patients with liver disease, active infection or malignancy, Patients with kidney disease from nondiabetic cause, Gastrointestinal absorption disorders, Sensitivity to drug components, Pregnant or lactating women

Intervention groups
Sixty patients with diabetic nephropathy are divided into two groups of 30 people. The treatment group receives "Qurs-e Tabasheer" along with their standard medication and the control group receives placebo (placebo that is similar in shape, color and other characteristics with the drug) along with their standard medication.

Main outcome variables
Fasting blood sugar level; Serum creatinine; Urinary albumin; LDL; eGFR; BUN

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220224054116N1**
Registration date: **2022-05-16, 1401/02/26**
Registration timing: **registered_while_recruiting**

Last update: **2022-05-16, 1401/02/26**
Update count: **0**

Registration date
2022-05-16, 1401/02/26

Registrant information

Name
Reyhaneh Sekhavat

Name of organization / entity
Alborz university of medical sciences

Country
Iran (Islamic Republic of)

Phone
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Email address
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-05-07, 1401/02/17

Expected recruitment end date
2023-05-07, 1402/02/17

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Effect of Qurs-e Tabasheer, a traditional Persian formula, on blood glucose and renal complications in patients with diabetic nephropathy, a randomized controlled trial

Public title
Effect of a traditional medicine "Qurs-e Tabasheer" on diabetes and diabetic nephropathy

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with diabetes and diabetic nephropathy Patients receiving a stable dose of ACEI or ARB eGFR between 15 and 30 (stage 4 CKD) Albuminuria more than 30 mg/day Patients over 18 years old

Exclusion criteria:
Patients with liver disease, active infection, malignancy Patients with kidney disease from nondiabetic cause Problems with nutrient absorption in gastrointestinal tract Sensitivity to drug components Pregnant or lactating women

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Multi-digit codes (barcodes) are written on the packages that only the main person in charge of the research can open the codes if necessary and specify the type of medicine. The codes are arranged in such a way that in the first ten codes, five packages contain one of the drugs and the other five packages contain the second drug. The same proportion is arranged in the second ten codes to the sixth ten codes. (Balanced Block Randomization) This type of design provides the conditions for intermediate tests, So that after the execution of each complete block, statistical tests can be performed, and if the result is reached and the difference between the two groups is significant, and the test power is maintained, the study can be stopped. In this study, random assignment of individuals to the intervention and control groups is performed using the Balanced Block Randomization technique. Due to the fact that the blocks considered in this study are ten blocks, we use Stata software to produce random number chains from 1 to 6 to reach the desired sample size. Preparation of randomly assigned sequences of individuals and their placement in sealed envelopes and numbered with a five-digit serial number is done by a third party who had no role in the design of the study. All envelopes have a random five-digit serial number that opens immediately after completing the basic information and tests and assigns individuals to the intervention or control group.

Blinding (investigator's opinion)
Double blinded

Blinding description
The drug (Qurs-e Tabashir) and placebo (which does not have the active ingredients) are packed in packages containing ten cans. They are both completely similar to each other in terms of size, shape and color. Each box is assigned a code consisting of numbers and letters. These codes are distributed based on a table of random numbers between the drug and placebo groups and the researcher and the patient are not aware of it. In this study, participants, clinical caregivers, researchers, and outcome evaluators are blinded.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research ethics committees of Alborz University of Medical Sciences

Street address
Office of the Ethics Committee, second floor, Vice chancellor for Research and Technology, Saffarian Alley, Golshahr Blvd, Karaj

City
Karaj

Province
Alborz

Postal code
3198764653

Approval date
2022-02-01, 1400/11/12

Ethics committee reference number
IR.ABZUMS.REC.1400.319

Health conditions studied

1

Description of health condition studied
Diabetes, Diabetic nephropathy

ICD-10 code
E11.2

ICD-10 code description
Type 2 diabetes mellitus with kidney complications

Primary outcomes

1

Description
Fasting blood sugar
Timepoint
At the beginning of the study and at the end of the 12th week after starting the medication
Method of measurement
Blood test

2

Description
Serum creatinine
Timepoint
At the beginning of the study and at the end of the 12th week after starting the medication
Method of measurement
Blood test

3

Description
LDL cholesterol (Low Density Lipoprotein)
Timepoint
At the beginning of the study and at the end of the 12th week after starting the medication
Method of measurement
Blood test

4

Description
Urinary albumin
Timepoint
At the beginning of the study and at the end of the 12th week after starting the medication
Method of measurement
Urine test

5

Description
Blood urea nitrogen
Timepoint
At the beginning of the study and at the end of the 12th week after starting the medication
Method of measurement
Blood test

6

Description
Estimated glomerular filtration rate(eGFR)
Timepoint
At the beginning of the study and at the end of the 12th week after starting the medication
Method of measurement
Calculating by the formula Cockcroft - Gault

Secondary outcomes

1

Description
Quality of Life score
Timepoint
At the beginning of the study and at the end of the 12th week after starting the medication
Method of measurement
Diabetes Quality of Life (DQOL) Questionnaire

2

Description
Sexual function score
Timepoint
At the beginning of the study and at the end of the 12th week after starting the medication
Method of measurement
FSFI Questionnaire for women and IIEF Questionnaire for men

Intervention groups

1

Description
Intervention group: This group receives Qurs-e Tabasheer (two tablets three times daily) for 12 weeks in addition to their standard treatment. Ingredients of Qurs-e Tabasheer are: Bambusa arundinacea 13.9% , Glycyrrhiza glabra 13.9% , Lactuca sativa 20.9% , Portulaca oleracea 20.9% , Coriandrum sativum 6.99% , Rosa damascena 6.99% , Armenian bole 4.2 درصد% , Acacia senegal2.8% , Punica granatum 2.8% , Santalum album 2.8% , Rhus coriaria 2.8% , Cinnamomum camphora 0.7% . This product is produced in the Pharmaceutics Laboratory of the Faculty of Pharmacy, Alborz University of Medical Sciences.
Category
Treatment - Drugs

2

Description
Control group: This group receives placebo tablet (two tablets three times daily) for 12 weeks in addition to their standard treatment. Placebo is similar to medicine in shape, color and other properties. The substance in the placebo is a harmless food substance (microcrystalline cellulose).
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Ali hospital

Full name of responsible person
Ramin Tajbakhsh
Street address
Valiasr Boulevard, Chamran Boulevard, Karaj
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Email
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Alborz University of Medical Sciences
Full name of responsible person
Dr Hatam Godini
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Vice chancellor for Research and Technology, Saffarian Alley, Golshahr Blvd, Karaj
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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
Alborz 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
Alborz University of Medical Sciences
Full name of responsible person
Mohammad Mahdi Ahmadian-Attari
Position
Assistant professor
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Other areas of specialty/work
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Person responsible for updating data

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Latest degree
A Level or less
Other areas of specialty/work
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Province
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Email
r.sekhavat77@gmail.com

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
Due to ethical considerations, participants' data will be published in general and without mentioning their names and personal information in the research article.
Study Protocol
Yes - There is 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
No - There is not 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
Yes - There is a plan to make this available
Title and more details about the data/document
Due to ethical considerations, participants' data will be published in general and without mentioning their names and personal information in the research article. Items will be published in the article. The general consent form is available at the University Vice Chancellor for Research.
When the data will become available and for how long
After the end of the study and publishing the article
To whom data/document is available
Researchers working in academic and scientific institutions, people working in industry
Under which criteria data/document could be used
Copying is prohibited. It is mandatory to follow the principles of referral.
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