

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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)

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+98 21 8807 6518

Email address

r.sekhavat77@gmail.com

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 senegal 2.8% , Punica granatum 2.8% , Santalum album 2.8% , Rhus coriaria 2.8% , Cinnamomum camphora 0.7% . This product is produced in the Pharmaceuticals 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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Alborz University of Medical Sciences
Full name of responsible person
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Vice chancellor for Research and Technology,
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Research@abzums.ac.ir

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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Contact

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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

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.

From where data/document is obtainable

Email of the person in charge of updating the information

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

sending an email

Comments