Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Oct 2026

Evaluation of the effect of deuterium-depleted water on lipid profile,liver enzymes and level of inflammatory markers including CPR and ESR in type 2 diabetic patients

Protocol summary

Study aim
Investigating the effect of deuterium-depleted water on lipid profile, liver enzyme levels, and inflammatory markers in type 2 diabetic patients.

Design
A parallel-group, double-blind, block-randomized, phase 3 clinical trial on 96 patients.

Settings and conduct
In this double-blind clinical trial, patients with type 2 diabetes referred to Luqman Hospital will be admitted. Background information including demographic characteristics, weight and height, clinical manifestations, laboratory parameters on the day of admission, the amount of calories consumed, the amount of daily sports activity and the type of drug treatment received are collected. Patients are randomly divided into two groups. The first group is treated with 1.5 liters (equivalent to the usual volume of drinking water consumed per day) of deuterium-depleted drinking water with a concentration of 80ppm as daily drinking water for 90 days, and the second group is treated with normal water as a placebo for a period of time and They will receive the same amount. Clinical and paraclinical tests are recorded before the start of treatment and then 90 days later.

Participants/Inclusion and exclusion criteria
Inclusion criteria: type 2 diabetic patients under oral treatment with HbA1c of 6.5 to 7.5%; no history of autoimmune disease. Exclusion criteria: failure to implement the study protocol and history of electrolyte disturbances.

Intervention groups
One group will be treated with 1.5 liters of drinking water depleted of deuterium with a concentration of 80 ppm for a period of 90 days, and the second group will receive normal water as a placebo for the same period and amount.

Main outcome variables
Liver enzymes; lipid profile; inflammatory markers

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20241018063407N1**
Registration date: **2024-10-27, 1403/08/06**
Registration timing: **registered_while_recruiting**

Last update: **2024-10-27, 1403/08/06**
Update count: **0**

Registration date
2024-10-27, 1403/08/06

Registrant information

Name
Mohammad Matin Rad

Name of organization / entity

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Iran (Islamic Republic of)

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matinsam10@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-10-22, 1403/08/01

Expected recruitment end date
2025-03-05, 1403/12/15

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of deuterium-depleted water on lipid profile,liver enzymes and level of inflammatory markers including CPR and ESR in type 2 diabetic patients

Public title

Investigating the effect of deuterium-depleted water in diabetic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Type 2 diabetes HbA1c equal to 6.5 to 7.5%

Exclusion criteria:

History of electrolyte disorder

Age

From **30 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are assigned to two groups using the random block method. The number of blocks will be 22 and in each block, two, four or six patients will be included in the study order. Random allocation of blocks of patients to two groups receiving drinking water and receiving water containing deuterium will be done through Sealed Envelope online software. By referring to https://www.sealedenvelope.com/simple-randomiser/v1/lists by specifying the total number of samples, the number of possible samples in each randomized block (2, 4 and 6 patients) randomization by online software is done For example, like the following output: block identifier block size sequence within block treatment 1 2 1 Group B 1 2 2 Group A 2 4 1 Group A 2 4 2 Group B 2 4 3 Group B 2 4 4 Group A 3 2 1 Group A 3 2 2 Group B ... which is the block number, the number of patients in the block, and the random assignment of each patient (with the corresponding number) to the treatment group. The randomized list of blocks will be placed in sealed envelopes and will be provided to the gastroenterologist on a daily basis.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, blinding will be done by coding bottles containing normal water and water depleted of deuterium, which are apparently the same, for the patients as well as part of the researchers who have the role of clinical caregivers and outcome assessors. Then these codes will be put in an envelope according to the number of patients and will be chosen randomly.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Beheshti University of Medical Sciences Faculty of Medicine

Street address

Arabi street, Velenjak

City

Tehran

Province

Tehran

Postal code

1411713135

Approval date

2024-10-08, 1403/07/17

Ethics committee reference number

IR.SBMU.MSP.REC.1403.422

Health conditions studied

1

Description of health condition studied

Type 2 diabetes

ICD-10 code

E11.9

ICD-10 code description

Type 2 diabetes mellitus without complications

Primary outcomes

1

Description

Liver enzymes

Timepoint

Before the intervention and 90 days later

Method of measurement

Blood sample

2

Description

Lipid profile

Timepoint
Before the intervention and 90 days later
Method of measurement
Blood sample

3

Description
Inflammatory markers
Timepoint
Before the intervention and 90 days later
Method of measurement
Blood sample and ELISA kit

Secondary outcomes

1

Description
Glucose
Timepoint
Before intervention and 90 days later
Method of measurement
Blood sample

2

Description
Triglycerides
Timepoint
Before intervention and 90 days later
Method of measurement
Blood test

3

Description
Total Cholesterol
Timepoint
Before intervention and 90 days later
Method of measurement
Blood test

Intervention groups

1

Description
Intervention group: The group treated with 1.5 liters (equivalent to the usual volume of drinking water consumed per day) of deuterium-depleted drinking water with a concentration of 80 ppm as daily drinking water for 90 days
Category
Treatment - Drugs

2

Description
Control group: Ordinary water receiver
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Loghman Hospital
Full name of responsible person
Omidvar Rezaei
Street address
Kargar street
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1333635445
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
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Arabi street, Velenjak
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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Mohammad Matinrad

Position
Resident

Latest degree
Specialist

Other areas of specialty/work
Internal Medicine

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Assistant professor

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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
Confidentiality and privacy of patients

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is 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
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
Study protocol, statistical analysis map, study design, clinical study report will be available

When the data will become available and for how long
After the publication of the article

To whom data/document is available
Researchers, medical students, professors

Under which criteria data/document could be used
If used for future research and in compliance with the principles of referencing

From where data/document is obtainable
The corresponding author is Dr. Azam Erfani Far erfanifarazam@yahoo.com

What processes are involved for a request to access data/document
Send the request to the responsible author and outline the reason for the request

Comments