

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The effect of Dapagliflozin on body composition in patients with type 2 Diabetes

Protocol summary

Registration timing: **prospective**

Study aim

Study of changes in blood sugar, lipid profile levels, body weight, fat mass, and muscle mass in diabetic subjects before and three months after starting dapagliflozin

Last update: **2026-07-13, 1405/04/22**

Update count: **0**

Registration date

2026-07-13, 1405/04/22

Design

This is a single-group study involving patients with type 2 diabetes who will receive dapagliflozin daily for 3 months, without blinding or randomization. Phase 2 will be conducted on 37 diabetic patients, and body composition tests will be measured before and after the end of the drug treatment period.

Registrant information

Name

Vahid Radmehr

Name of organization / entity

Country

Iran (Islamic Republic of)

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Settings and conduct

In this study, patients with type 2 diabetes, without blinding and as directed by their physician after a blood test, will undergo a body composition test on two occasions, before and after three months of taking Dapagliflozin.

Recruitment status

Not yet recruiting

Funding source

Participants/Inclusion and exclusion criteria

Inclusion criteria: Type 2 diabetic patients with blood sugar above 126 mg/dL. Exclusion criteria: Patients unable to perform body analysis tests, including surgery or pregnancy.

Expected recruitment start date

2026-08-23, 1405/06/01

Expected recruitment end date

2027-08-23, 1406/06/01

Intervention groups

Diabetic patients receiving Dapagliflozin (5 mg daily) for three months

Actual recruitment start date

empty

Actual recruitment end date

empty

Main outcome variables

Dapagliflozin, age, body weight, sex, fasting blood sugar, hemoglobin A1c Lipid profile including: cholesterol, low-density lipoprotein, high-density lipoprotein, triglycerides Fat mass, muscle mass, total body water, body mass index

Trial completion date

empty

General information

Scientific title

The effect of Dapagliflozin on body composition in patients with type 2 Diabetes

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251108067913N2**

Registration date: **2026-07-13, 1405/04/22**

Public title

Studying the effect of Dapagliflozin in Diabetes

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Diabetic patients who will start taking dapagliflozin
Exclusion criteria:
Diabetic patients who have undergone surgery and are not able to perform a body composition test
Female patients who are pregnant
Taking medications related to weight loss
Having other diseases, such as cancer

Age
From **18 years** old to **75 years** old
Gender
Both

Phase
2
Groups that have been masked
No information

Sample size
Target sample size: **37**
More than 1 sample in each individual
Number of samples in each individual: **2**
Performing a physical analysis and other blood factors test before starting and three months after taking dapagliflozin

Randomization (investigator's opinion)
N/A

Randomization description
Blinding (investigator's opinion)
Not blinded

Blinding description
Placebo
Not used

Assignment
Single

Other design features
This study is designed as a before-and-after clinical trial study in which the studied factors will be measured in one group at two times, before and three months after starting dapagliflozin.

Secondary Ids

empty

Ethics committees

1
Ethics committee
Name of ethics committee
Ethics committee of Jundishapur University of Medical Sciences
Street address
Jundishapur University of Medical Sciences, North Esfand St, Farvardin Blvd
City
Ahvaz
Province
Khouzestan
Postal code
61357-15794
Approval date
2025-08-12, 1404/05/21

Ethics committee reference number
IR.AJUMS.REC.1404.539

Health conditions studied

1
Description of health condition studied
Diabetes
ICD-10 code
E11.9
ICD-10 code description
Type 2 diabetes mellitus without complications

Primary outcomes

1
Description
Fasting blood glucose
Timepoint
Before the start of the intervention and three months after the start of the intervention
Method of measurement
Auto analyzer device

2
Description
Glycosylated hemoglobin A1c
Timepoint
Before the start of the intervention and three months after the start of the intervention
Method of measurement
Auto analyzer device

3
Description
Body fat mass
Timepoint
Before the start of the intervention and three months after the start of the intervention
Method of measurement
Body analysis device

4
Description
Total body muscle mass
Timepoint
Before the start of the intervention and three months after the start of the intervention
Method of measurement
Body analysis device

5
Description
Total body water
Timepoint
Before the start of the intervention and three months

after the start of the intervention

Method of measurement

Body analysis device

Secondary outcomes

1

Description

Low-density lipoprotein

Timepoint

Before the start of the intervention and three months
after the start of the intervention

Method of measurement

Auto analyser device

2

Description

High-density lipoprotein

Timepoint

Before the start of the intervention and three months
after the start of the intervention

Method of measurement

Auto analyser device

3

Description

Triglyceride

Timepoint

Before the start of the intervention and three months
after the start of the intervention

Method of measurement

Auto analyser device

4

Description

Cholestrol

Timepoint

Before the start of the intervention and three months
after the start of the intervention

Method of measurement

Auto analyser device

Intervention groups

1

Description

Intervention group: Diabetic patients will receive dapagliflozin (C21H25ClO6), Kimia Pharmaceutical Company (Foxibet), a sodium-glucose cotransporter inhibitor in the renal proximal tubule, 5 mg daily after breakfast for three months. In these patients, the desired factors will be measured once before starting dapagliflozin and three months after the start of the intervention.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan hospital

Full name of responsible person

Vahid Radmehr

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Abdollah Rafiei

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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

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Vahid Radmehr

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiology

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Person responsible for updating data

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Latest degree

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Other areas of specialty/work

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Other areas of specialty/work

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Phone

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

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

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

Not applicable

Data Dictionary

Not applicable