Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

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

Protocol summary

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

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.

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.

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.

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

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

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20251108067913N2**
Registration date: **2026-07-13, 1405/04/22**
Registration timing: **prospective**

Last update: **2026-07-13, 1405/04/22**
Update count: **0**

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

Registrant information
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Recruitment status
recruiting
Funding source

Expected recruitment start date
2026-08-23, 1405/06/01
Expected recruitment end date
2027-08-23, 1406/06/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

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

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 (C21H25Cl1O6), 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

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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
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Person responsible for updating data

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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
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