

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of empagliflozin and dapagliflozin in the incidence of urinary tract infection in women with diabetes

Protocol summary

Study aim

To compare the incidence of urinary tract infections in women with diabetes treated with empagliflozin or dapagliflozin, in order to determine which drug has a better safety profile in this regard.

Design

Clinical trial with two parallel groups treated with diabetes drugs dapagliflozin and empagliflozin on 84 patients; randomized, double-blind study, analyzed using SPSS or SAS statistical software.

Settings and conduct

Convenience sampling will be used. Women with diabetes who refer to Imam Reza Hospital in Tehran will be identified and placed in study groups. Participants will be randomly divided into two groups treated for diabetes with dapagliflozin and empagliflozin. The study is a double-blind, randomized study, and patients and investigators will not be informed of the research.

Participants/Inclusion and exclusion criteria

Statistical population: Women with diabetes. Selection criteria: Women with diabetes (type 1 or 2). Agreement to participate in the study and take the study medications. No physical or psychological barriers to active participation in the study. Women over 18 years of age; Exclusion criteria: intolerance or negative reaction to the study medications; serious side effects from the medications; pregnancy.

Intervention groups

Women with diabetes will be divided into two groups. Participants will be prescribed the study drug (empagliflozin and dapagliflozin); periodic follow-ups will be conducted (after three months) to assess the effect of the drugs on the rate of urinary tract infections.

Main outcome variables

Incidence of confirmed urinary tract infection (UTI) in diabetic women treated with empagliflozin compared with dapagliflozin

General information

Reason for update

Acronym

TDS

IRCT registration information

IRCT registration number: **IRCT20250129064554N1**

Registration date: **2025-04-15, 1404/01/26**

Registration timing: **registered_while_recruiting**

Last update: **2025-04-15, 1404/01/26**

Update count: **0**

Registration date

2025-04-15, 1404/01/26

Registrant information

Name

sara kazm nadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4420 6090

Email address

saranadi1402@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-10-11, 1403/07/20

Expected recruitment end date

2025-06-26, 1404/04/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of empagliflozin and dapagliflozin in the incidence of urinary tract infection in women with diabetes

Public title

Comparison of two drugs, empagliflozin and dapagliflozin, in the development of urinary tract infections in women with high blood sugar

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Women with diabetes (type 1 or 2) Women over 18 years of age No physical or psychological barriers to active participation in the study. Consent to participate in the study and take the study medication.

Exclusion criteria:

Intolerance or adverse reaction to the study drugs. Having serious side effects from the drugs. Being pregnant

Age

From **18 years** old

Gender

Female

Phase

4

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size

Target sample size: **84**

More than 1 sample in each individual

Number of samples in each individual: **2**

Necessary tests are performed to measure the variables under investigation. This includes urine test results to assess the level of urinary tract infection before and after receiving the medication.

Randomization (investigator's opinion)

Randomized

Randomization description

Participants are randomly assigned to different groups. For this purpose, patients referring to the treatment center are divided into two groups without knowledge: those treated for diabetes with the drug dapagliflozin and those treated with the drug empagliflozin. In order to be more confident in deducing the results of the randomized double-blind study, patients and investigators (those who perform the urine infection test, complications, and effectiveness of the drugs) are not informed of the research.

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to be more confident in drawing conclusions from the results of a randomized double-blind study, patients and investigators (those who test for urinary tract infections, complications, and the effectiveness of medications) are not informed of the research.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Islamic Republic of Iran Army University of Medical Sciences

Street address

AJA university of medical sciences, Etemad zadeh street, Fatemi Gharbi street

City

Tehran

Province

Tehran

Postal code

۱۴۱۱۷۱۸۵۴۱

Approval date

2024-10-02, 1403/07/11

Ethics committee reference number

IR.AJAUMS.REC.1403.153

Health conditions studied

1

Description of health condition studied

Urinary tract infection

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Percentage of people who get urinary tract infections.

Timepoint

Three months after taking the drug

Method of measurement

Urinalysis and urine culture test

Secondary outcomes

1

Description

Percentage of people who experience drug side effects.

Timepoint

Three months after taking the medication

Method of measurement

Urinalysis and urine culture

2

Description

Percentage of people whose blood sugar is controlled with the study drugs.

Timepoint

Three months after taking the medication

Method of measurement

Urinalysis and urine culture

Intervention groups

1

Description

Intervention group:Empagliflozin.

Category

Prevention

2

Description

Intervention group:Dapagliflozin.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital (AS) 501 Aja

Full name of responsible person

Sara kazemnadi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Artesh 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

Artesh University of Medical Sciences

Proportion provided by this source

5

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

Artesh University of Medical Sciences

Full name of responsible person

Sarah Keshkari

Position

Assistant Professor, Army University of Medical Sciences

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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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

Undecided - It is not yet known if there will be 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

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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available