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)

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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

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

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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 drugĨ

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

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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
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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