

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of efficacy and safety of empagliflozin with placebo in patients with idiopathic edema

Protocol summary

Study aim

Comparison of efficacy and safety of empagliflozin with placebo in patients with idiopathic edema

Design

A clinical trial with a control group, with parallel groups, double-blind, randomized, on 70 patients. The randomization of patients will be done with the block randomization method using block of size 4

Settings and conduct

This research is a randomized double-blind controlled clinical trial that will be conducted on patients with idiopathic edema referred to nephrology clinics in Ahvaz and Dezful, and to prevent bias until the end of the research, all members of the treatment and research team will not be aware of the codes (drug type) and after the end of the treatment, the codes will be opened

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients over 18 years of age who suffers from generalized edema and in the diagnostic examinations, there is no justifying disorder and the cause of generalized edema for the patient; The patient does not take drugs that cause edema. Non-inclusion criteria: patients who do not want to cooperate and participate in the research or withdraw during the research; menopause (in women)

Intervention groups

Intervention group: There are patients who are treated with empagliflozin tablets. Control group: There are patients who receive placebo.

Main outcome variables

The amount of edema

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230314057712N1**

Registration date: **2023-08-19, 1402/05/28**

Registration timing: **registered_while_recruiting**

Last update: **2023-08-19, 1402/05/28**

Update count: **0**

Registration date

2023-08-19, 1402/05/28

Registrant information

Name

Shokouh Shayanpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 916 311 4638

Email address

shayanpour-sh@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-21, 1402/02/01

Expected recruitment end date

2024-04-20, 1403/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy and safety of empagliflozin with placebo in patients with idiopathic edema

Public title

The effect of empagliflozin in patients with idiopathic edema

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients over 18 years of age who refer due to generalized edema The patient does not take drugs that cause edema In the diagnostic investigations, there are no disorders, including kidney, heart, liver, thyroid, etc. There should be no justification and cause of generalized edema for the patient

Exclusion criteria:
Patients who do not want to cooperate and participate in the research Patients with diseases such as advanced renal failure, liver failure, chronic or recurrent UTI Patients with immune deficiency or diabetes Patients who use drugs that interfere with the intervention process

Age
From **18 years** old

Gender
Both

Phase
4

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
At the beginning of the research, the patients will be divided into two groups of case and control (35 people each) through block randomization with spss type 23 software and using blocks of size 4, and block randomization is for the purpose of making sure Exactly equal number of participants are included in the intervention and control group at consecutive but equal time intervals

Blinding (investigator's opinion)
Double blinded

Blinding description
The placebo will be completely with the same color and similar to the original drug and its packaging will be completely similar to the original drug, and then the drug (empagliflozin) and the placebo will be coded by the pharmacist. To prevent bias until the end of the research, all members of the treatment and research team will be unaware of the codes, and the codes will be unlocked after the treatment process is over

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz jundishapur University of Medical Sciences

Street address

Imam Khomeini Hospital; Azadegan street

City

Ahvaz

Province

Khouzestan

Postal code

61936673111

Approval date

2023-03-11, 1401/12/20

Ethics committee reference number

IR.AJUMS.REC.1401.590

Health conditions studied

1

Description of health condition studied

Idiopathic edema

ICD-10 code

R60.9

ICD-10 code description

Edema, unspecified

Primary outcomes

1

Description

The amount of edema

Timepoint

At the beginning of the study, 2, 6 and 12 weeks after starting the mentioned drug

Method of measurement

TANITA body analysis device

Secondary outcomes

1

Description

The amount of physical activity in the International Physical Activity Questionnaire

Timepoint

before the intervention and then at the end of the second, sixth and twelfth weeks

Method of measurement

International Physical Activity Questionnaire

Intervention groups

1

Description

Intervention group: For patients in the main group, empagliflozin 10 mg tablets manufactured by Abidi Pharmaceutical Company in Iran are prescribed. One empagliflozin tablet with 50 cc of water will be prescribed once a day and after lunch for 12 weeks. To control the correct use of the drug and placebo by the patients, the drug will be delivered to the patients on a weekly basis and at the end of the week, the empty blisters will be collected from the patients and counted. If more than 20% of the drug or placebo is not consumed, the patient will be removed from the study.

Category

Treatment - Drugs

2

Description

Control group: Control group patients will be prescribed 10 mg of placebo drug along with 50 cc of water once a day after lunch for 12 weeks. It will be delivered and at the end of the week, the empty blisters will be collected from the patients and counted. The placebo will be produced at Jundishapur Faculty of Pharmacy in Ahvaz, and it will be similar to the original drug in terms of all physical and appearance characteristics and packaging. The placebo compounds include It will be Avisel

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz Imam Khomeini Hospital

Full name of responsible person

Shokouh Shayanpour

Street address

24 Metery street, East Sahely highway

City

Ahvaz

Province

Khouzestan

Postal code

6193673166

Phone

+98 916 311 4638

Email

shayanpour-sh@ajums.ac.ir

2

Recruitment center

Name of recruitment center

Ahvaz Golestan Hospital

Full name of responsible person

Shokouh Shayanpour

Street address

Golestan Hospital; Golestan district

City

Ahvaz

Province

Khouzestan

Postal code

15794-61357

Phone

+98 916 311 4638

Email

shayanpour-sh@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mehrnoosh Zakerkish

Street address

24 metery street, East Sahely highway

City

Ahvaz

Province

Khouzestan

Postal code

6193673166

Phone

+98 916 311 4638

Fax

+98 916 311 4638

Email

shayanpour-sh@ajums.ac.ir

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

Shokouh Shayanpour

Position

Assistant Professor of Nephrology

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

Street address

Imam Khomeini Hospital; Azadegan St. (24 Metery)

City

Ahvaz

Province

Khouzestan

Postal code

6193673166

Phone

+98 916 311 4638

Fax

Email

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Shokouh Shayanpour

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Person responsible for updating data

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Shokouh Shayanpour

Position

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Latest degree

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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

Still undecided - no release schedule yet.

Study Protocol

No - There is not 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