Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Aug 2026

Evaluation of the Protective Effect of Empagliflozin on Doxorubicin-induced Cardiotoxicity in Breast Cancer patients; A Randomized Clinical Trial

Protocol summary

Study aim

Determining the protective effect of empagliflozin on doxorubicin-induced cardiotoxicity in patients with breast cancer

Design

This clinical trial has two parallel control groups (placebo recipients) and empagliflozin recipients, which is randomized, double-blind, and in phase 3 and is conducted on 152 patients with breast cancer. Permuted block randomization method is used for randomization.

Settings and conduct

This study is being conducted at the chemotherapy unit of Ayatollah Rouhani Hospital, Babol University of Medical Sciences. The clinical trial is conducted in a double-blind manner. The drug and placebo are completely similar in color, smell, and taste, and the patient, physician, and evaluator will not know the type of drug.

Participants/Inclusion and exclusion criteria

Includes all patients with breast cancer in stages 1 to 3 who referred to Ayatollah Rouhani Hospital in Babol during 2025-2026 and whose breast cancer diagnosis was confirmed and who are candidates for the use of a chemotherapy regimen containing doxorubicin.

Intervention groups

Intervention: The intervention group or those receiving empagliflozin will take 10 mg of empagliflozin daily for 2 months (equivalent to 4 cycles of doxorubicin treatment) during the period of receiving standard chemotherapy for breast cancer treatment until one week after the last chemotherapy session. Control group: The control group is breast cancer patients who are treated with doxorubicin but are given placebo instead of empagliflozin. The control group or those receiving placebo will take the placebo combination daily for 2 months (equivalent to 4 cycles of doxorubicin treatment) during the period of receiving standard chemotherapy for breast cancer treatment until one week after the last chemotherapy session.

Main outcome variables

Changes in echocardiographic patterns in strain echocardiography

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250526065902N2**
Registration date: **2025-11-15, 1404/08/24**
Registration timing: **registered_while_recruiting**

Last update: **2025-11-15, 1404/08/24**
Update count: **0**

Registration date

2025-11-15, 1404/08/24

Registrant information

Name

Sahar khosravi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3233 1305

Email address

s.khosravi@mubabol.ac.ir

Recruitment status

recruiting

Funding source

Expected recruitment start date

2025-10-23, 1404/08/01

Expected recruitment end date

2026-10-23, 1405/08/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the Protective Effect of Empagliflozin on Doxorubicin- induced Cardiotoxicity in Breast Cancer patients; A Randomized Clinical Trial

Public title
Evaluation of the Protective Effect of Empagliflozin on Doxorubicin- induced Cardiotoxicity in Breast Cancer patients
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with newly diagnosed breast cancer, stage 1 to 3, who are candidates for a chemotherapy regimen containing doxorubicin. Reading and signing the informed consent form to participate in the clinical trial People over the age of 18. People who are able to consume food. Negative pregnancy test in women of childbearing age
Exclusion criteria:
A history of cancer in the past that has received cardiotoxic drugs such as doxorubicin History of chest radiotherapy LVEF less than 50% before starting treatment Being treated for heart failure and taking medications to treat heart failure History of congenital heart disease or history of coronary artery disease History of more than moderate valvular heart disease based on history and records History of hypertension or history of symptomatic hypotension or SBP less than 100 on the first or second visit History of atrial fibrillation History of cardiomyopathy and use of heart failure medications based on the medical history in the file History of stroke Cognitive and neurological disorders Simultaneous participation in another clinical trial Allergy to any of the materials used in the trial Liver disease or LFTs greater than 3 times ULN at first visit Kidney failure in the form of a GFR less than 30 or requiring dialysis, diagnosed at the first visit History of diabetic ketoacidosis History of surgery on the gastrointestinal tract or a gastrointestinal disorder that interferes with drug absorption Patients who have used SGLT2I drugs for at least 3 months before referral Alcohol or drug abuse
Age
From **18 years** old
Gender
Female

Phase
3
Groups that have been masked

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

Sample size
Target sample size: **152**
Randomization (investigator's opinion)
Randomized
Randomization description
To randomize patients into two treatment groups with drug (A) and placebo (B), the permuted block randomization method is used. The block size is 4 and the ratio of groups in each block is (1:1). The generation of the random sequence is designed by the methodologist and is performed using the online software Seed envelope.com. In order to conceal the treatment process, a random code is assigned to each of the treatments generated in the above random sequence and written on the cans containing the drug and placebo. After the patients are allocated, the above code is entered on the file.
Blinding (investigator's opinion)
Triple blinded
Blinding description
The drug and placebo are completely similar in color, smell, and taste, and the patient, doctor, and evaluator will not know the type of drug. If side effects are observed, the drug code of the same person will be reopened. Otherwise, the codes will be reopened at the end of the study and after analysis. The placebo is manufactured by Dr. Abidi's company in the same packaging, shape, and weight as empagliflozin tablets and is available to the participating pharmacist. Patients go to the pharmacy based on the code assigned to them, which the pharmacist is unaware of, and receive the placebo.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Babol University of Medical Sciences
Street address
Ganj Afrooz
City
Babol
Province
Mazandaran
Postal code
4717647745
Approval date
2025-10-05, 1404/07/13
Ethics committee reference number
IR.MUBABOL.HRI.REC.1404.110

Health conditions studied

1

Description of health condition studied
Heart failure
ICD-10 code
I50
ICD-10 code description
Heart failure

Primary outcomes

1

Description
Changes in echocardiographic patterns in strain echocardiography
Timepoint
Before the start of the study and one week after the last chemistry session
Method of measurement
Echocardiography

Secondary outcomes

1

Description
Cardiac ejection fraction (EF)
Timepoint
Before the start of the study and one week after the last chemistry session
Method of measurement
Echocardiography

Intervention groups

1

Description
Intervention group: The intervention group, or those receiving empagliflozin, will take a 10 mg empagliflozin tablet daily for 2 months (equivalent to 4 courses of doxorubicin treatment) during the course of conventional chemotherapy for breast cancer treatment until one week after the last chemotherapy session.
Category
Prevention

2

Description
Control group: The control group, or placebo group, takes a placebo compound daily for 2 months during the course of receiving conventional chemotherapy for breast cancer treatment until one week after the last chemotherapy session.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Rouhani Hospital
Full name of responsible person
Sahar Khosravi
Street address
Ganj Afrooz
City
Babol
Province
Mazandaran
Postal code
4717647745
Phone
+98 11 3219 9591
Fax
+98 11 3219 0181
Email
s.khosravi@mubabol.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Reza Ghadimi
Street address
Ganj Afrooz
City
Babol
Province
Mazandaran
Postal code
4717647745
Phone
+98 11 3219 9591
Fax
+98 11 3219 0181
Email
info@mubabol.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Babol 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

Babol University of Medical Sciences

Full name of responsible person

Sahar Khosravi

Position

Faculty member

Latest degree

Subspecialist

Other areas of specialty/work

Hematology

Street address

Ganj Afrooz

City

Babol

Province

Mazandaran

Postal code

4717647745

Phone

+98 11 3219 9591

Email

saharkhosravi77@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Sahar Khosravi

Position

Assistant

Latest degree

Subspecialist

Other areas of specialty/work

Hematology

Street address

Kheshavarz

City

Babol

Province

Mazandaran

Postal code

4717647745

Phone

+98 11 3233 1305

Fax

Email

s.khosravi@mubabol.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Sahar Khosravi

Position

Assistant

Latest degree

Subspecialist

Other areas of specialty/work

Hematology

Street address

Kheshavarz

City

Babol

Province

Mazandaran

Postal code

4717647745

Phone

+98 11 3233 1305

Fax

Email

s.khosravi@mubabol.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The participant data file, study protocol, statistical analysis map, and clinical study report will be published in the form of an article.

When the data will become available and for how long

After the article is published

To whom data/document is available

Public

Under which criteria data/document could be used

The data can be used if the article is referenced.

From where data/document is obtainable

The information published in the relevant article can be accessed by sending an email to the corresponding author.

What processes are involved for a request to access data/document

They can be accessed by sending an email to the author responsible for the article and explaining the reason for using the documentation.

Comments