

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Comparison of metformin and placebo on breast mammography density in healthy women over 40 years

Protocol summary

Study aim

The effect of metformin on breast density

Design

A concealed, randomized, blinded, placebo-controlled clinical trial with a parallel-group design of 146 patients

Settings and conduct

This study will be conducted on eligible participants attending Arash Hospital and would give consent to participate in the study. Before the randomization, random blood glucose, liver and kidney function, and CBC tests will be checked. Participants will be randomly divided into intervention and control groups. None of the research team members (except epidemiologist) and participants will be informed about the random allocation process. The mammography breast density was recorded before and 6 months after intervention. Participants will be monitored every two weeks during the intervention period and they will be advised to keep their routine diet during the study and inform the researcher if they need to use any other medications, supplements or other therapies.

Participants/Inclusion and exclusion criteria

Inclusion criteria: women over 40 years of age. Non-inclusion criteria: use of hormonal or metabolic drugs, breast cancer, hormonal disorders, metabolic and internal diseases, pregnancy or breastfeeding, having contraindications, a history of unwanted and intolerable side effects for metformin drug

Intervention groups

Intervention group: Includes 73 people who will take metformin 500 mg tablets twice a day for 6 months.
Control groups: Includes 73 people who will take placebo tablets twice a day for 6 months.

Main outcome variables

Breast density

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100706004329N9**
Registration date: **2020-12-15, 1399/09/25**
Registration timing: **registered_while_recruiting**

Last update: **2020-12-15, 1399/09/25**

Update count: **0**

Registration date

2020-12-15, 1399/09/25

Registrant information

Name

Sadaf Alipour

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

00982177888751 - 00982177883195

Email address

salipour@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-24, 1399/09/04

Expected recruitment end date

2021-05-25, 1400/03/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of metformin and placebo on breast mammography density in healthy women over 40 years

Public title

The effect of metformin on breast density

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Female gender Age over 40 years

Exclusion criteria:

Suspicion of malignancy Used of drugs that affect metabolic status, such as weight, glucose, and lipid-lowering agents During the study or three months before the study History of breast cancer Proven or suspected pregnancy and lactation during the intervention Other medical conditions, such as cardiovascular disease, epilepsy, renal or hepatic disorders Contraindications for metformin use (such as hypersensitivity to biguanides, acidemia, heart disease, alcohol consumption, gastroparesis, hepatic disease, hyperthyroidism or hypothyroidism, severe iron deficiency anemia, renal impairments) History of unwanted and intolerable side effects of metformin (such as abdominal pain, chest pain, chills, cholestasis, diarrhea, dizziness, increased liver enzymes, severe headache, hepatitis, hypoglycemia, megaloblastic anemia, myalgia, nausea, Palpitations, rash, rash, vomiting) Suffering from hormonal disorders and metabolic diseases such as hypo or hyperthyroidism, metabolic syndrome, diabetes, severe hyperlipidemia, galactorrhea

Age

From **40 years** old

Gender

Female

Phase

3

Groups that have been masked

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

Sample size

Target sample size: **146**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization process is performed by a simple random method with a random table of numbers

Blinding (investigator's opinion)

Triple blinded

Blinding description

The random allocation list will be provided exclusively to the epidemiologist. To conceal the random allocation process, 146 drugs envelopes with the same shape will be numbered with a 10-digit random code, which is the drug identification number. The code recognition key will be only available to the methodologist. All envelopes will be placed in a box in the order and on the basis of the random allocation list and will be available to the corresponding member. When the breast surgeon declares the patient's eligibility, the methodologist will

provide the doctor with the envelope. The treatment plan will be selected based on the type of treatment mentioned in the envelope. In this study, the placebo is quite similar to the main drug (metformin). None of the patients should be aware of the type and treatment process they are seeking. Also, the person evaluating the outcomes is a third party who is unaware of the random allocation process and the type of treatment. The statistician who will analyze the data will be unaware of the type of intervention performed

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Tehran University of Medical Sciences

Street address

Qods St, Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2020-11-11, 1399/08/21

Ethics committee reference number

IR.TUMS.IKHC.REC.1399.307

Health conditions studied**1****Description of health condition studied**

Breast density

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Breast density

Timepoint

At the beginning of the study (before the intervention) and six months after the intervention

Method of measurement

Mammography scan

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Consumption of 500 mg oral Metformin tablets twice a day for 6 months

Category

Treatment - Drugs

2

Description

Control group: Consumption of oral placebo tablets (that are completely similar to the metformin tablets) twice a day for 6 months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Arash Women 's Hospital

Full name of responsible person

Sadaf Alipour, Professor of Surgery

Street address

Arash Women 's Hospital, Rashid Ave, Resalat Highway, Tehranparse

City

Tehran

Province

Tehran

Postal code

1653915981

Phone

+98 21 7771 9922

Email

hosparash@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Mohammad Ali Sahraeyan

Street address

Qods St, Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 8163 3698

Email

vcr@tums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Sadaf Alipour

Position

Tehran

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

Street address

Arash Women 's Hospital, Rashid Ave, Resalat Highway, Tehranparse

City

Tehran

Province

Tehran

Postal code

1653915981

Phone

00982177888751 - 00982177883195

Fax

+98 21 7788 3196

Email

salipour@sina.tums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

D.r Sadaf Alipour

Position

Professor of Surgery

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

Street address

Arash Women 's Hospital, Rashid Blvd, Resalat
Highway, Tehranparse

City

Tehran

Province

Tehran

Postal code

1653915981

Phone

+98 21777719922

Fax

Email

salipour@Sina.tums.ac.ir

Web page address

Highway, Tehranparse,Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1653915981

Phone

009821777719922

Fax

Email

salipour@Sina.tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

D.r Sadaf Alipour

Position

Professor of Surgery

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

Street address

Arash Women 's Hospital, Rashid Ave, Resalat

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