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
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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
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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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
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Tehran
Latest degree
Medical doctor
Other areas of specialty/work
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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