Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jun 2026

Evaluation of the Effect of Metformin on Breast Fibroadenoma

Protocol summary

Study aim
Determination of the effect of metformin on breast Fibroadenoma (FA)

Design
A concealed, randomized, blinded, placebo-controlled clinical trial with a parallel group design of 206 patients

Settings and conduct
This study will be conducted on eligible participants attending to Arash woman's 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 randomly be divided into two groups of intervention and control. None of the research team members (except epidemiologist) and participants will be informed about the random allocation process. A medication reminder table will also be given to participants to monitor the tablets consumption. Study variables will be measured and recorded before and 6 months after the beginning of the study, by using standard tools and questionnaires. Participants will be monitored every two weeks during the intervention period. Participants 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
Women aged 18 to 50 with breast FAs smaller than 3 cm in size will be included and in the cases of menopause, obesity, use of hormonal or metabolic drugs, and dietary supplements, herbal medicine, having a special diet, breast cancer, hormonal disorders, metabolic and internal diseases, pregnancy or breastfeeding, and having contraindications, or a history of unwanted and intolerable side effects for metformin drug, will be excluded.

Intervention groups
Intervention group:103 participants who will Intake metformin 500 mg tablets twice a day for 6 months
Control group: 103 participants who will Intake placebo tablets twice a day for 6 months

Main outcome variables
Size of the fibroadenoma

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20100706004329N7**
Registration date: **2018-10-07, 1397/07/15**
Registration timing: **registered_while_recruiting**

Last update: **2018-10-07, 1397/07/15**
Update count: **0**

Registration date
2018-10-07, 1397/07/15

Registrant information

Name
Sadaf Alipour

Name of organization / entity
Tehran University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-09-23, 1397/07/01

Expected recruitment end date
2019-09-23, 1398/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Evaluation of the Effect of Metformin on Breast Fibroadenoma

Public title
Effect of Metformin on Breast Fibroadenoma

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Aged between 18 and 50 years old Unilateral or bilateral fibroadenoma of the breast smaller than 3 cm in size, detected by examination and ultrasound. (Diagnostic criteria: 1. in patients under the age of 40 years and patients with masses smaller than 2 cm, the diagnosis will be based on the typical examination and ultrasonographic scan. 2. in patients over 40 years with any size of the mass and patients with masses above 2 cm, the diagnosis will be based on a typical examination, ultrasonographic scan, and pathological investigation of the mass.

Exclusion criteria:
Menopause Body mass index greater than 29.9 kg / m2 Use of hormonal medications (such as estrogen, progesterone, GnRH agonist, GnRH antagonist, clomiphene, tamoxifen, letrozole, danazol, contraceptive pills, progesterone IUDs, DHEA) and drugs that affect metabolic status, such as weight, glucose, and lipid-lowering agents Regular consumption of nutritional, medicinal and herbal supplements (such as phytoestrogenic plant compounds, vitamin-rich foods, minerals such as zinc, calcium and ..., multivitamins, vitamins A, E, D, inositol, omega-3, 6) Breast cancer or history of breast cancer A family history of breast cancer in first-degree relatives Hormonal disorders and metabolic diseases such as hypo or hyperthyroidism, metabolic syndrome, diabetes, severe hyperlipidemia - galactorrhea and the pituitary microadenoma 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)

Age
From **18 years** old to **50 years** old

Gender
Female

Phase
3

Groups that have been masked

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

Sample size
Target sample size: **206**

Randomization (investigator's opinion)
Randomized

Randomization description
We will use the blocked randomization method by using a web-based random number generator at www.sealedenvelope.com. Blocks size are considered to be 6.

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, 206 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. None of the patients would 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, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1417653761

Approval date

2018-08-18, 1397/05/27

Ethics committee reference number

IR.TUMS.VCR.REC.1397.357

Health conditions studied

1

Description of health condition studied

fibroadenoma of breast

ICD-10 code

D24

ICD-10 code description

Benign neoplasm of breast

Primary outcomes

1

Description

Size of the Fibroadenoma

Timepoint

At the beginning of the study (before the intervention) and 6 months after starting the intervention.

Method of measurement

sonography

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

Dr Sadaf Alipour

Street address

No. 162 Alley (Abdul Majid), Shahid Baghdarnia Street (North Rashid), Shahid Bagheri Highway, Resalat Highway, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Mohammad Ali Sahraian

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6th floor, Central University, Qods St, Keshavarz Blv, Tehran, Iran

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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

Full name of responsible person
Dr Sadaf Alipour

Position
Associate professor

Latest degree
Subspecialist

Other areas of specialty/work
General Surgery

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Person responsible for scientific inquiries

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Person responsible for updating data

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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
Not applicable