

# 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)

##### Phone

00982177888751 - 00982177883195

##### Email address

salipour@sina.tums.ac.ir

##### 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 / m<sup>2</sup>  
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](http://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

**City**

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**Province**

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**Postal code**

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**Phone**

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**Email**

salipour@sina.tums.ac.ir

**Web page address**

<http://arash.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 Sahraian

**Street address**

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

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resdeputy@tums.ac.ir

**Web page address**

<http://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**

Dr Sadaf Alipour

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

General Surgery

**Street address**

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## Person responsible for updating data

### 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

### 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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**Fax**

## 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