# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Jun 2026

## Evaluation of the Effect of Metformin on Breast Fibrocystic Changes

## Protocol summary

**Study aim**
Determination of the effect of metformin on breast fibrocystic changes

**Design**
A concealed, randomized, blinded, placebo-controlled clinical trial with a parallel group design of 148patients

**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. Demographic characteristics, dietary intake, physical activity level, and anthropometric indexes will be measured and recorded by a trained interviewer. FCC related symptoms such as pain, nodularity, and tenderness of the breast will be assessed by the surgeon. The radiologist will complete the FCC ultrasound scoring table. 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**
Women of reproductive age with breast fibrocystic changes will be included and cases with menopause, obesity, use of hormonal or metabolic drugs, 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 not be included

**Intervention groups**
Intervention: Includes 74people who will take metformin 500 mg tablets twice a day for 6 months Control: Includes 74people who will take placebo tablets twice a day for 6 months

**Main outcome variables**
Mastalgia; Nodularity; Tenderness; ultrasonographic findings

## General information

**Reason for update**
**Acronym**
**IRCT registration information**
IRCT registration number: **IRCT20100706004329N6**
Registration date: **2018-10-06, 1397/07/14**
Registration timing: **registered_while_recruiting**

Last update: **2018-10-06, 1397/07/14**
Update count: **0**

**Registration date**
2018-10-06, 1397/07/14

**Registrant information**

**Name**
Sadaf Alipour
**Name of organization / entity**
Tehran University of Medical Sciences
**Country**
Iran (Islamic Republic of)
**Phone**
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**Recruitment status**
**Recruitment complete**
**Funding source**

**Expected recruitment start date**
2018-09-23, 1397/07/01
**Expected recruitment end date**
2019-04-21, 1398/02/01
**Actual recruitment start date**
empty
**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Evaluation of the Effect of Metformin on Breast Fibrocystic Changes

**Public title**
Metformin in Fibrocystic Changes of Breast

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Age of fertility FCC diagnosis based on history, examination and ultrasound.

**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 During the study or three months before the study began Hormonal disorders and metabolic diseases such as hypo or hyperthyroidism, metabolic syndrome, diabetes, severe hyperlipidemia, galactorrhea 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 **15 years** old to **55 years** old

**Gender**
Female

**Phase**
3

**Groups that have been masked**

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

**Sample size**
Target sample size: **148**

**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, 148 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 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, 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.1397.358

## Health conditions studied

**1**

**Description of health condition studied**
Fibrocystic Changes of the braest

**ICD-10 code**
N64.9

**ICD-10 code description**

Disorder of breast, unspecified

## Primary outcomes

### 1

**Description**
Mastalgia
**Timepoint**
At the beginning of the study (before the intervention), three months and six months after the intervention began
**Method of measurement**
Questionnaire (Visual Analog Scale)

### 2

**Description**
Breast nodularity
**Timepoint**
At the beginning of the study (before the intervention), three months and six months after the intervention began
**Method of measurement**
Clinical examinations by the surgeon and registration in a standard checklist designed by the researchers

### 3

**Description**
Breast Tenderness
**Timepoint**
At the beginning of the study (before the intervention), three months and six months after the intervention began
**Method of measurement**
Clinical examinations by the surgeon and registration in a standard checklist designed by the researchers

### 4

**Description**
ultrasound findings related to fibrocystic changes in the breast
**Timepoint**
At the beginning of the study (before the intervention) and six months after the intervention began
**Method of measurement**
By ultrasonographic scan and recording on a standard checklist designed by the researchers

## 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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**Postal code**
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## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Tehran University of Medical Sciences
**Full name of responsible person**
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**Email**

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**

Arash women's hospital, No. 162 Alley (Abdul Majid), Shahid Baghdarnia Street (North Rashid), Shahid Bagheri Highway, Resalat Highway, Tehran, Iran

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## Person responsible for scientific inquiries

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**Latest degree**

Subspecialist

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## Person responsible for updating data

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**Full name of responsible person**

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**Position**

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**Latest degree**

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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