

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Evaluation of the Protective Effect of Metformin against the Tamoxifen Induced Changes on Endometrium and Ovaries in Women with Breast Cancer

Protocol summary

Study aim

Determine the Protective Effect of Metformin against the Tamoxifen on endometrium and ovary in women with breast cancer

Design

A randomized clinical trial with the parallel groups, with control group, double-blind, phase 3 with 100 patients. The block randomization method will be designed by using "www.sealedenvelope.com"

Settings and conduct

This study will be conducted at Arash Women's hospital on patients taking tamoxifen due to breast cancer. Participants will be randomly assigned into two groups; group 1 (metformin) and group 2 (placebo). Once before and then once six months after the start of the intervention, the endometrial thickness and number of the ovarian cysts will be assessed by ultrasound.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Adjutant treatment of breast cancer with tamoxifen; Normal pelvic exam, Performance state 0-2. Exclusion criteria: Systemic diseases; use of systemic hormone therapy 6 months ago; alcohol consumption; diabetes; advanced breast cancer; having any cancer or malignancy except for breast cancer during the last three years; atypical hypoplasia or endometrial cancer; abnormal ovarian cysts with the possibility of malignancy on ultrasound; contraindications to the use of metformin (eg: allergy to biguanides, acidosis, heart disease; gastroparesis, liver disease, hyperthyroidism or hypothyroidism, severe iron deficiency anemia, renal impairment)

Intervention groups

Intervention groups: Metformin 500 mg, oral tablets, three times a day for 6 months Control group: participants in the control group will take three placebo tablets daily for 6 months

Main outcome variables

Ovarian cyst

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140820018866N9**

Registration date: **2021-03-18, 1399/12/28**

Registration timing: **prospective**

Last update: **2021-03-18, 1399/12/28**

Update count: **0**

Registration date

2021-03-18, 1399/12/28

Registrant information

Name

Afsaneh Tehranian

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 7788 3283

Email address

afsanehtehranian@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-04, 1400/01/15

Expected recruitment end date

2022-09-06, 1401/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of the Protective Effect of Metformin against the Tamoxifen Induced Changes on Endometrium and Ovaries in Women with Breast Cancer

Public title
Evaluation of the Protective Effect of Metformin against the Tamoxifen Induced Changes on Endometrium and Ovaries

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
 Adjutant treatment of breast cancer with tamoxifen
 Normal pelvic exam Performance state 0-2
Exclusion criteria:
 Serious diseases, heart or endocrine or other systemic diseases Use of systemic hormone therapy during past 6 months Alcohol consumption Diabetes Advanced breast cancer Having any cancer or malignancy other than breast cancer during the last three years Atypical hypoplasia or endometrial cancer abnormal ovarian cysts with the possibility of malignancy on ultrasound
 Contraindications for using metformin (eg: allergy to biguanides, acidosis, heart disease, alcohol consumption, gastroparesis, liver disease, hyperthyroidism or hypothyroidism, severe iron deficiency anemia, renal impairment) Unbearable and dangerous side effects of metformin (such as: abdominal pain, chest pain, chills, cholestasis, severe diarrhea, dizziness, increased liver enzymes, severe headache, hepatitis, hypoglycemia, megaloblastic anemia, myalgia, palpitations, Skin rash and rash, vomiting)

Age
No age limit

Gender
Female

Phase
3

Groups that have been masked

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

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
The considered sample size is 100, with 50 participants in each group. The block randomization method will be designed by using "www.sealedenvelope.com". The size of blocks considered is 4. The random allocation list for patients will be solely available to the epidemiologist. To hide the random allocation process, 100 card sequences of treatments will be written accordingly, and then the

cards will be placed inside sealed envelopes. A 10-digit random code will be written on each packet as the patient's identification number. When the physician announces the eligibility of a patient, the methodologist will provide the envelope.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The physician, patient, and outcome assessor are unaware of the type of intervention

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 Science

Street address

Tehran University of Medical Science, Qods Street, Keshavarz Boulevard

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2021-01-27, 1399/11/08

Ethics committee reference number

IR.TUMS.IKHC.REC.1399.427

Health conditions studied

1

Description of health condition studied

ovarian cysts

ICD-10 code

N83.2

ICD-10 code description

Other and unspecified ovarian cysts

Primary outcomes

1

Description

Endometrial thickness

Timepoint

Before and after treatment

Method of measurement

Vaginal ultrasoun

2

Description

Number and characteristic of ovarian cyst

Timepoint

Before and after treatment

Method of measurement

Vaginal ultrasound

Secondary outcomes

1

Description

Changes in liver enzymes

Timepoint

Before and after treatment

Method of measurement

laboratory test

2

Description

Chenges in weight

Timepoint

Before and after treatment

Method of measurement

Scales

3

Description

changes in weight

Timepoint

Before and after treatment

Method of measurement

Laboratory test

Intervention groups

1

Description

Intervention group: Metformin 500 mg ,oral tablets, three times a day for 6 months.

Category

Treatment - Drugs

2

Description

Control group: participants in the control group will take three placebo tablets daily for 6 months.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Arash women's hospital

Full name of responsible person

Dr Afsaneh Tehranian

Street address

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

City

Tehran

Province

Tehran

Postal code

1653915981

Phone

+98 21 7788 3283

Fax

+98 21 7788 3196

Email

afsanehtehranian@yahoo.com

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. Sahraeiyan

Street address

Tehran University of Medical Sciences, Keshavarz blvd., Ghods st.

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 8838 8988

Email

resdeputy@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
Afsaneh Tehranian
Position
Associate professor
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Tehran University of Medical Sciences, Qhods st.,
Keshavarz blvd.
City
Tehran
Province
Tehran
Postal code
1653915981
Phone
+98 21 7788 3283
Fax
+98 21 7788 3293
Email
afsanehtehranian@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Afsaneh Tehranian
Position
Associate professor
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Tehran University of Medical Sciences, Qhods st.,
Keshavarz blvd.
City
Tehran
Province
Tehran
Postal code
1653915981

Phone
+98 21 7788 3283
Fax
+98 21 7788 3293
Email
afsanehtehranian@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Afsaneh Tehranian
Position
Associate professor
Latest degree
Medical doctor
Other areas of specialty/work
Street address
Tehran University of Medical Sciences, Qhods st.,
Keshavarz blvd.
City
Tehran
Province
Tehran
Postal code
1653915981
Phone
+98 21 7788 3283
Fax
+98 21 7788 3293
Email
afsanehtehranian@yahoo.com

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