

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of using metformin on ki-67 tumor marker gene expression in endometrial cancer patients referred to Imam Hossein and Mahdie hospital, between 1401-1402

Protocol summary

Study aim

Determining the effect of metformin on ki-67 gene expression in patients with endometrial cancer

Design

Two arm parallel group, double blind randomized trial, phase 1-2, over 40 patients, Excel software rand function was used for randomization.

Settings and conduct

All patients referred to Imam Hossein or Mahdiah hospitals in Tehran between 1401-1402 with a diagnosis of endometrial cancer and with no exclusion criteria, are first randomly divided into two groups: control or metformin. The patient and the researcher themselves are unaware of which group each person belongs to. Each volunteer patient fills a form containing basic personal information, demographic information, risk factors, the date of first diagnosis, and the recommended time for surgery and an endometrial sample prepared by pipelle biopsy or curettage is sent to the pathology department of Imam Hossein (AS) Hospital for examination and staining of ki-67 and p-53 (examined by one pathologist). The drug box and placebo are distributed. The day of surgery is independent of the study, and after surgery, a sample of each patient is sent to the pathology for re-examination of ki-67.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All women with endometrial carcinoma pathology referred to Mahdiah / Imam Hossein (AS) hospital and are in the list of staging surgery of this center. Exclusion criteria: pregnancy, diabetes or using blood sugar control drugs, renal or hepatic failure, cancers in the last 5 years, chemotherapy or hormone therapy last 3 months, allergy to or contraindications of using biguanides.

Intervention groups

After randomization, patients are given a box containing 100 metformin 500 tablets or a placebo.

Main outcome variables

The extent of changes in ki-67 gene expression in tissue samples of patients with endometrial cancer before and after receiving metformin

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220409054463N1**

Registration date: **2022-04-27, 1401/02/07**

Registration timing: **prospective**

Last update: **2022-04-27, 1401/02/07**

Update count: **0**

Registration date

2022-04-27, 1401/02/07

Registrant information

Name

Minoo Rostami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6615 9710

Email address

drminoorstmi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-21, 1401/03/31

Expected recruitment end date

2023-06-21, 1402/03/31

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of using metformin on ki-67 tumor marker gene expression in endometrial cancer patients referred to Imam Hossein and Mahdie hospital, between 1401-1402

Public title
Metformin as a chemotherapeutic agent

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
All women with endometrial carcinoma pathology, regardless of age and histological stage, who have referred to Mahdiah / Imam Hossein (AS) Medical Center between 1401-1402 and are on the list of staging surgery of this center.
Exclusion criteria:
Pregnancy Diabetes or the use of metformin or other blood sugar control drugs Liver or kidney dysfunction Simultaneous cancers over the last 5 years Use of chemotherapy drugs or hormone therapy during the last 3 months Any allergy to Biguanides or contraindications to the use of this class of drugs

Age
From **20 years** old

Gender
Female

Phase
1-2

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple individual randomization, using the Rand function of Excel software

Blinding (investigator's opinion)
Double blinded

Blinding description
The study is double-blind, and the patient, caregiver, and researcher do not know which category the patient is in (metformin or placebo).

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Koodakiar street, Shahid Beheshti medical University

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2022-04-15, 1401/01/26

Ethics committee reference number

IR.SBMU.REC.1401.37

Health conditions studied

1

Description of health condition studied

Endometrial carcinoma

ICD-10 code

C54.1

ICD-10 code description

Malignant neoplasm of endometrium

Primary outcomes

1

Description

Changes in the expression of ki-67 gene in tissue samples of endometrial cancer after using metformin

Timepoint

Before treatment and on the day of surgery

Method of measurement

Ki-67 tissue staining (IHC)

2

Description

Changes in p-53 gene expression in endometrial cancer tissue samples after metformin use

Timepoint

Before treatment and on the day of surgery

Method of measurement

P-53 tissue staining (IHC)

3

Description

Determining the effect of metformin on tumor size

reduction

Timepoint
Before treatment and on the day of surgery

Method of measurement
Measurement of mass during diagnosis by ultrasound and by the surgeon

4

Description
Determining the effect of metformin use in reducing body mass index

Timepoint
Before treatment and on the day of surgery

Method of measurement
Measuring Body Mass Index (weight over height²)

Secondary outcomes

1

Description
Changes in p-53 gene expression in endometrial cancer tissue samples after metformin use

Timepoint
Before treatment and on the day of surgery

Method of measurement
P-53 tissue staining (IHC)

2

Description
Determining the effect of metformin on tumor size reduction

Timepoint
Before treatment and on the day of surgery

Method of measurement
Measurement of mass during diagnosis by ultrasound and by the surgeon

3

Description
Determining the effect of metformin use in reducing body mass index

Timepoint
Before treatment and on the day of surgery

Method of measurement
Measuring Body Mass Index (weight over height²)

Intervention groups

1

Description
Intervention group: In this study, we intend to refer patients with endometrial cancer who have been referred to Mahdiah / Imam Hossein (AS) Hospital, and are on the list of gynecological surgeries of this hospital, regardless of histological and surgical staging, for at least 4 weeks. Metformin 500 mg tablets are given orally every 8 hours. For each volunteer a form containing basic personal

information and demographic information including age, BMI at the time of admission and day of surgery, pregnancy and parity, underlying disease, smoking, menopause, date of first diagnosis And the suggested time for surgery is filled. Patients with the above criteria, after filling out the form related to the initial information, an endometrial sample prepared by pipelle biopsy or curettage will be sent to the pathology department of Imam Hossein Hospital for examination and staining of ki-67 and p-53. And is examined by one pathologist. Patients are given a box of 100 metformin 500 tablets. Explanations about how to take the drug, its side effects, including gastrointestinal symptoms and symptoms of hypoglycemia, etc., and a contact number to communicate with patients participating in the project will be given to the patient by the medical team. All patients will receive treatment according to standard guidelines, and metformin will be discontinued 48 hours before anesthesia to prevent the risk of lactic acidosis.

Category

Treatment - Drugs

2

Description

Control group: In this study, we intend to refer patients with endometrial cancer who have been referred to Mahdiah / Imam Hossein (AS) Hospital, and are on the list of gynecological surgeries of this hospital, regardless of histological and surgical staging, for at least 4 weeks. Metformin 500 mg tablets are given orally every 8 hours. For each volunteer a form containing basic personal information and demographic information including age, BMI at the time of admission and day of surgery, pregnancy and parity, underlying disease, smoking, menopause, date of first diagnosis And the suggested time for surgery is filled. Patients with the above criteria, after filling out the form related to the initial information, an endometrial sample prepared by pipelle biopsy or curettage will be sent to the pathology department of Imam Hossein Hospital for examination and staining of ki-67 and p-53. And is examined by one pathologist. Patients are given a box of 100 placebo tablets similar to metformin 500 tablets. Explanations about how to take the drug, its side effects, including gastrointestinal symptoms and symptoms of hypoglycemia, etc., and a contact number to communicate with patients participating in the project will be given to the patient by the medical team. All patients will receive treatment according to standard guidelines, and metformin will be discontinued 48 hours before anesthesia to prevent the risk of lactic acidosis.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mahdie hospital

Full name of responsible person

Minoo Rostami

Street address

Shoush square, Fadaian-e-islam street

City

Tehran

Province

Tehran

Postal code

1185817311

Phone

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Email

mahdiyeh_hospital@sbmu.ac.ir

Web page address

<https://mmc.sbm.ac.ir>

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti 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

2

Recruitment center**Name of recruitment center**

Imam Hossein Hospital

Full name of responsible person

Minoo Rostami

Street address

Shahid Madani street, after subway station

City

Tehran

Province

Tehran

Postal code

1617763141

Phone

+98 21 7733 3430

Email

info@ehmc.ir

Web page address

<https://www.ehmc.ir/>

Person responsible for general inquiries

Contact**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Minoo Rostami

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Koodakiar street, Shahid beheshti medical university

City

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Phone

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Fax**Email**

drminoorstmi@gmail.com

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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Grant name**Grant code / Reference number**

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Minoo Rostami

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Koodakiar street, Shahid beheshti medical university

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Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Minoo Rostami
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
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Koodakiar street, Shahid beheshti medical university
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Data collected for the primary outcome measure will be shared.

When the data will become available and for how long

6 month after publication

To whom data/document is available

Data are available for people working in academic institutions and businesses.

Under which criteria data/document could be used

Data could be used for meta-analysis.

From where data/document is obtainable

An e-mail in English should be sent to the main executor of the project (Dr. Minoo Rostami) and in addition to introducing the relevant person and organization, the type of data analysis and how to use it in the study should be fully mentioned. drminoorstmi@gmail.com

What processes are involved for a request to access data/document

After sending the email to the above address, within 10 working days, the email will be answered and if the use of information, etc. is clear, the information will be provided to the researchers.

Comments