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, beween 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 refered to Imam Hossein or Mahdieh 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 Mahdieh / 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, beween 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 Mahdieh / 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 height^2)

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 height^2)

Intervention groups

1

Description

Intervention group: In this study, we intend to refer patients with endometrial cancer who have been referred to Mahdieh / 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 Mahdieh / 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
+98 21 5506 2628
Email
mahdiyeh_hospital@sbmu.ac.ir
Web page address
https://mmc.sbmu.ac.ir

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/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
Koodakiar street, Shahid Beheshti medical university
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 23871
Email
info@sbmu.ac.ir
Grant name
Grant code / Reference number
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

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
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Full name of responsible person
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Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
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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
Gynecology and Obstetrics
Street address
Koodakiar street, Shahid beheshti medical university
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+98 21 6615 9710
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drminoorstmi@gmail.com

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