

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of metformin on the early outcome of patients undergoing ovarian cancer chemotherapy

#### Protocol summary

##### Study aim

The aim of this study was to evaluate the effect of metformin on the early outcome of patients undergoing ovarian cancer chemotherapy.

##### Design

Clinical trial with control group, with parallel groups, randomized, phase 3, not blinded on 90 patients.

##### Settings and conduct

Patients will be examined after end of chemotherapy and serum level of cancer antigen 125 will be measured and patients will be scanned by computed tomography. Respond to treatment to assess the early outcome will be evaluated 3 months after end of the chemotherapy period and is based on the findings of computed tomography scan and measurement of serum level of cancer antigen 125; and recurrence of the disease will be evaluated by increasing the level of serum level of cancer antigen 125 or diagnosis of new mass in computed tomography scan and clinical examination.

##### Participants/Inclusion and exclusion criteria

Patients with confirmed epithelial ovarian cancer with a pathology report who are over 18 years of age, have a serum cancer antigen 125 level above 35 mg/dL, and candidates for laparotomy and tumor surgery staging will be enrolled. Patients with diabetes, gastrointestinal disorders, renal failure, metformin intolerance, previous history of chemotherapy, other cancers, and serum level of cancer antigen 125 equal to or less than 35 mg/dL will be excluded.

##### Intervention groups

Intervention: Metformin starts with a daily dose of 500 mg and during one week the dose will be increased to 1500 mg daily in three divided doses (500 mg every 8 hours). This group will also receive carboplatin – paclitaxel periodically (every 21 days). Control: They will receive carboplatin – paclitaxel periodically (every 21 days).

##### Main outcome variables

Serum level of cancer antigen 125

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120922010901N7**

Registration date: **2020-07-26, 1399/05/05**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-07-26, 1399/05/05**

Update count: **0**

##### Registration date

2020-07-26, 1399/05/05

##### Registrant information

##### Name

Parvin Mostafa Gharebaghi

##### Name of organization / entity

Women's Reproductive Health Research Center,  
Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1553 9161

##### Email address

gharabagh.p@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-07-22, 1399/05/01

##### Expected recruitment end date

2020-10-22, 1399/08/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**

The effect of metformin on the early outcome of patients undergoing ovarian cancer chemotherapy

**Public title**

The effect of metformin in patients with ovarian cancer

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Confirmed ovarian epithelial cancer with pathology report Serum cancer antigen 125 level above 35 mg/dl Laparotomy and surgical tumor staging candidate

**Exclusion criteria:**

Diabetes Gastrointestinal disorders Kidney failure Metformin intolerance Having other cancers in addition to ovarian epithelial cancer Previous history of chemotherapy Serum cancer antigen 125 level equal and lower than 35 mg/dl

**Age**

From **18 years** old

**Gender**

Female

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **90**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Patients will be divided into intervention and control groups using even and odd numbers, respectively. The number zero is considered as even.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Tabriz University of Medical Sciences

**Street address**

Faculty of medicine, Daneshgah Ave. Pish-Ghadam Ave.

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5157695774

**Approval date**

2020-06-28, 1399/04/08

**Ethics committee reference number**

IR.TBZMED.REC.1399.309

**Health conditions studied****1****Description of health condition studied**

Serum CA125 changes

**ICD-10 code**

R97.1

**ICD-10 code description**

Elevated cancer antigen 125 [CA 125]

**Primary outcomes****1****Description**

Response to treatment

**Timepoint**

Three months after the intervention

**Method of measurement**

Serum level of cancer antigen 125

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: Metformin starts with a daily dose of 500 mg and during one week the dose will be increased to 1500 mg daily in three divided doses (500 mg every 8 hours). This group will also receive carboplatin - paclitaxel periodically (every 21 days).

**Category**

Treatment - Drugs

**2****Description**

Control group: Will receive carboplatin - paclitaxel periodically (every 21 days).

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Alzahra hospital

**Full name of responsible person**

Parvin Mustafa gharabaghi

**Street address**

Bagh\_e shomal square

**City**

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**Province**

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**Postal code**

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Pm\_gharabaghi@yahoo.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Elahe Saheb Olad Madarek

**Street address**Women's Reproductive Health Research Center,  
Alzahra hospital, Artesh-jonoobi Ave.**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5138665793

**Phone**

+98 41 3554 1221

**Email**

wrhrcenter@tbzmed.ac.ir

**Web page address**<https://wrhrc.tbzmed.ac.ir/>**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Tabriz 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**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr.Parvin Mostafa Gharabaghi

**Position**Gynecologist, fellow of Women's Oncology / Associate  
Professor Obstetrics Midwifer**Latest degree**

Subspecialist

**Other areas of specialty/work**

Gynecology and Obstetrics

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**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

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**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Parvin Mostafa Gharabaghi

**Position**

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**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

**Title and more details about the data/document**

Study data related to the primary outcome variable will be shared.

**When the data will become available and for how long**

Access starts 6 months after the results publication.

**To whom data/document is available**

Obstetricians and gynecology specialists will be allowed to receive data.

**Under which criteria data/document could be used**

Study data will be available after obtaining permission from the Vice Chancellor for Research.

**From where data/document is obtainable**

The data can be obtained after coordination with the person in charge of updating the trial.

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

Obtain permission from the person in charge of updating the trial

**Comments**