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 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 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
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Iran (Islamic Republic of)
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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
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Women's Reproductive Health Research Center, Alzahra hospital, Artesh-jonoobi Ave.
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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
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Person responsible for updating data

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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 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 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