

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

combination of metformin and standard chemotherapy decreases recurrence rate of epithelial ovarian cancers

Protocol summary

Summary

objectives:Metformin has been recently reported to be beneficial as an adjunctive therapy in cancer recurrence in patients receiving chemotherapy. In this study, efficacy of metformin in combination with chemotherapy will be investigated in patients with ovarian cancer.

design: randomized clinical trial setting and conduct:70 women with histopathologic diagnosis of epithelial ovarian carcinoma undergone total abdominal hysterectomy and bilateral salpingo-oophorectomy in shahid faghihi hospital(shiraz)march 2011 to march 2015 were randomized into case and control group;30 patients receiving standard chemotherapy plus metformin as the case group and 40 patients receiving only standard chemotherapy as the control group. including

criteria:women with histopathologic diagnosis of epithelial ovarian carcinoma undergone total abdominal hysterectomy and bilateral salpingo-oophorectomy in shahid faghihi hospital(shiraz)march 2011 to march 2015 were included. those with the following criteria were excluded from the study: diabetic patients; patients with liver or gastrointestinal disorders or renal failure; patients unable to tolerate metformin; patients who received neoadjuvant chemotherapy before cytoreductive surgery; patients whose ovarian cancer is secondary to other cancers intervention;; the study group received 500 mg metformin three times a day in addition to standard chemotherapy sessions after surgical resection of the primary ovarian cancer. The control group received only the standard chemotherapeutic agents after surgery. main outcome measures: 1-monthly serum ca125 level 2-monthly pelvic ultrasound 3-monthly pelvic examination

Registration date: **2016-07-31, 1395/05/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-07-31, 1395/05/10

Registrant information

Name

Shohreh Roozmeh

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 74 3333 7251

Email address

shohreh.roozmeh@yums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2011-02-28, 1389/12/09

Expected recruitment end date

2013-02-28, 1391/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016022726788N1**

Scientific title

combination of metformin and standard chemotherapy decreases recurrence rate of epithelial ovarian cancers

Public title

chemotherapy plus metformin reduces recurrence of ovarian cancer

Purpose

Treatment

Inclusion/Exclusion criteria

all women with histopathologic diagnosis of epithelial ovarian carcinoma undergone total abdominal hysterectomy and bilateral salpingo-oophorectomy in shahid faghihi hospital(shiraz)march 2011 to march 2015 were included. those with the following criteria were excluded from the study: diabetic patients; patients with liver or gastrointestinal disorders or renal failure; patients unable to tolerate metformin; patients who received neoadjuvant chemotherapy before cytoreductive surgery; patients whose ovarian cancer is secondary to other cancers

Age

From **30 years** old to **80 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Medical ethics committee of Shiraz University of Medical

Street address

Zand st

City

Shiraz

Postal code

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

153/11/41/9p

Health conditions studied

1

Description of health condition studied

Ovarian cancer

ICD-10 code

C56

ICD-10 code description

Malignant neoplasm of ovary

Primary outcomes

1

Description

2 year recurrence rate

Timepoint

2 years

Method of measurement

Visit

Secondary outcomes

1

Description

Disease free survival

Timepoint

2-4 years

Method of measurement

Visit

Intervention groups

1

Description

In the study group, a 500mg daily dose of metformin was started (gradually increasing to 1500 mg daily divided three times a day within a week) in addition to standard carboplatin-paclitaxel regimen

Category

Treatment - Drugs

2

Description

The control group receives standard chemotherapy regimen.in stage 1 or 2 of cancer they recieved 3-6 courses of carboplatin-paclitaxel regimen chemotherapy while patients in stage 3 or 4 recieved 6-9 courses .

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

OB/GYN department, Shahid Faghihi hospital, Shiraz

Full name of responsible person

Shohreh Roozmeh

Street address

OB/GYN department, Shahid Faghihi hospital, Zand ST, Shiraz

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor of research, Shiraz University of Medical Sciences

Full name of responsible person

Zohreh Tavana

Street address

Department of Obstetrics and Gynecology, Shahid Faghihi Hospital, Zand street

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor of research, Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Shohreh Roozmeh

Position

MD

Other areas of specialty/work

Street address

Department of OB/GYN, Shahid Faghihi hospital, Zand ST, Shiraz

City

Shiraz

Postal code

Phone

+98 71 3235 1087

Fax

Email

shohreh.roozmeh@yums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Shohreh Roozmeh

Position

Gynecologist

Other areas of specialty/work

Street address

Department of Obstetrics and Gynecology, Shahid Faghihi hospital, Zand ST, Shiraz

City

Shiraz

Postal code

Phone

+98 71 3235 1087

Fax

Email

shohreh.roozmeh@yums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Shohreh Roozmeh

Position

Gynecologist

Other areas of specialty/work

Street address

Department of Obstetrics and Gynecology, Shahid Faghihi Hospital, Zand street

City

Shiraz

Postal code

Phone

+98 71 3235 1087

Fax

Email

shohreh.roozmeh@yums.ac.ir

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report
empty
Analytic Code

empty
Data Dictionary
empty