

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

Comparison the results of combination platinum based neoadjuvant chemotherapy regimens using gemcitabin/ciplatin with carboplatin/paclitaxel in advanced stage ovarian cancer patients; A RCT

Protocol summary

Summary

The objective of this randomized, clinical trial is to investigate the results of combination platinum based neoadjuvant chemotherapy regimens using gemcitabin/cisplatin or carboplatin/paclitaxelin in advanced stage serous ovarian cancer patients, who have been undergone interval cytoreductive surgery and evaluation of intraoperative and early postoperative complications. In this study, 206 patients with advanced serous ovarian cancer, Figo stage III and IV, and ascites volume more than 500cc which was found by ultrasonography and CT SCAN, and meet the inclusion/exclusion criteria will be recruited and randomly assigned into intervention groups. Histologic diagnosis will be made by paracentesis. The patients in the first group will receive gemcitabin/cisplatin but those in the second group will receive carboplatin/paclitaxel. First, in each group, chemotherapy is done for three cycles, then interval cytoreductive surgery is carried out and primary outcome measures will be evaluated with the measurement of preoperative CA-125 levels, diameter of target lesions, the volume of residual tumor , the volume of ascites , amount of bleeding during surgery, surgery duration and death during surgery .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201203225283N3**

Registration date: **2012-06-28, 1391/04/08**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-06-28, 1391/04/08

Registrant information

Name

Manizheh Sayyah Melli

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

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

Expected recruitment start date

2009-11-22, 1388/09/01

Expected recruitment end date

2011-01-20, 1389/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the results of combination platinum based neoadjuvant chemotherapy regimens using gemcitabin/ciplatin with carboplatin/paclitaxel in advanced stage ovarian cancer patients; A RCT

Public title

Comparison the results of combination platinum based neoadjuvant chemotherapy regimens using gemcitabin/ciplatin with carboplatin/paclitaxel in advanced stage ovarian cancer patients; A RCT

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Patients with advanced serous ovarian cancer Figo Stage III and IV; the volume of ascites, that is determined by ultrasound or CT scan, more than 500cc

Age

From **20 years** old to **90 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **206**

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

Tabriz University of medical Sciences

Street address

Golgasht Ave., Vice Chancellor deputy of Research,
Tabriz University of medical Sciences

City

Tabriz

Postal code

Approval date

2011-05-24, 1390/03/03

Ethics committee reference number

2537/4/5

Health conditions studied

1

Description of health condition studied

Patients with advanced serous ovarian cancer, Figo stage III and IV

ICD-10 code

c56

ICD-10 code description

Malignant neoplasm of ovary

Primary outcomes

1

Description

CA-125 levels

Timepoint

before surgery

Method of measurement

Lab measurement

2

Description

The volume of residual tumor

Timepoint

During surgery

Method of measurement

Clinical judgment

3

Description

The volume of ascites

Timepoint

During surgery

Method of measurement

Clinical estimation

4

Description

Bleeding

Timepoint

During surgery

Method of measurement

Clinical estimation

5

Description

Surgery duration

Timepoint

During surgery

Method of measurement

During surgery

6

Description

Death during surgery

Timepoint

During surgery

Method of measurement

observation

Secondary outcomes

1

Description

wound infection, dehiscence, nausea, vomiting, diarrhea, ileus, intestinal obstruction, hospital stay

Timepoint

24 h after surgery

Method of measurement

observation, ultrasonography, CT-scan

2**Description**

ascites collection

Timepoint

24 hours after surgery

Method of measurement

observation, ultrasonography, CT-scan

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

For first group, at first day combination of gemcitabine (1000 mg per square meter on days 1 and 8 IV during 30 minutes) and cisplatin (75 mg per square meter, IV) are administered. This protocol can be repeated every 21 days. This protocol is repeated every 21 days, and up to 3 courses of chemotherapy is done. Then patients undergo immediate interval debulking surgery.

Category

Treatment - Drugs

2**Description**

For group 2, combination of carboplatin (carboplatin at an area under the concentration-time curve (AUC) of 5-6 mg/mL/min IV over 1 hour and paclitaxel (175 mg per square meter IV over 3 hours) on the first day will be prescribed. This protocol is repeated every 21 days, and up to 3 courses of chemotherapy is done. Then patients undergo immediate interval debulking surgery.

Category

Treatment - Drugs

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

Alzahra Hospital

Full name of responsible person**Street address****City**

Tabriz

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

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

Full name of responsible person

Elaheh Ouladsahebmadarek

Street address

Alzahra Hospital, South ArteshAve., Tabriz, Iran.

City

Tabriz

Grant name

10506

Grant code / Reference number**Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Women's Reproductive Health Research Center, Tabriz
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**

Tabriz University of Medical Sciences

Full name of responsible person

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Full Professor

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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*