Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Assessment of efficacy of weekly paclitaxel as a neoadjuvant chemotherapy in advanced ovarian cancers

Protocol summary

Summary

Aim: The aim of this study is to determine the progression-free survival (PFS) rate following treatment with weekly paclitaxel and carboplatin as neoadjuvant therapy. Methods: This randomized clinical trial will conduct on 14 patients with stage IIIC and IV advanced ovarian carcinoma. After collecting data on patients' characteristics and cancer, the patients undergo neoadjuvant chemotherapy. Every neoadjuvant chemotherapy course is consisted of weekly paclitaxel (80 mg/m2) and carboplatin (AUC=6) every three weeks. All the patients receive the three courses of treatment and then undergo interval debulking surgery. After the surgery, patients with stage IIIC receive three other courses of chemotherapy and the other patients receive five other courses through the above-mentioned method. After every 21 days of treatment course, the patients will evaluated to investigate their response to treatment based on RECIST 1.1 criteria and side effects. Patients will followed up for at least six months and finally, PFS is measured from the start of treatment until relapse.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017050333789N1**
Registration date: **2017-06-30, 1396/04/09**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-06-30, 1396/04/09

Registrant information

Name

Shirin Haghighi

Name of organization / entity

Shahid Beheshti Uniersity of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 2243 2560

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Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2016-05-24, 1395/03/04

Expected recruitment end date

2017-05-25, 1396/03/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of efficacy of weekly paclitaxel as a neoadjuvant chemotherapy in advanced ovarian cancers

Public title

Assessment of efficacy of weekly paclitaxel chemotherapy in ovarian cancers

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age over 18yr; Ovarian cancer confirmed by biopsy and pathology; Advanced disease confirmed by CT scan (Stage III or IV); No previous history of chemotherapy; Good liver and lung functional status; No candidate for primary surgery due to underlying disease; Full access to patients medical documents; Patient satisfaction for study participation

Age
From **18 years** old
Gender
Female

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **14**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shahid Beheshti University of Medical Sciences
Street address
Velenjak St., Shahid Chamran Highway
City
Tehran
Postal code
1985717443
Approval date
2016-05-24, 1395/03/04
Ethics committee reference number
ir.sbmu.msp.rec.1395.70

Health conditions studied

1

Description of health condition studied
Advanced Ovarian Cancer
ICD-10 code
C56
ICD-10 code description
Malignant neoplasm of ovary

Primary outcomes

1

Description
Progression-free survival (PFS)
Timepoint
At the end of followup study
Method of measurement
Cancer free duration after end of tratment period

Secondary outcomes

1

Description
Anemia
Timepoint
After each 21 day treatment course
Method of measurement
CBC

2

Description
Neutropenia
Timepoint
After each 21 day treatment course
Method of measurement
CBC

3

Description
Trombocytopenia
Timepoint
After each 21 day treatment course
Method of measurement
CBC

4

Description
Neuropathy
Timepoint
After each 21 day treatment course
Method of measurement
Clinical Exam

Intervention groups

1

Description
All patients give three neoadjuant courses and undergo interval debulking surgery. Each course consists of weekly paclitaxel (80mg/m2) and carboplatin (AUC 6) each three weeks. Then, patients in St IIIC give three and other patients give five additional chemotherapy.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center

Taleghani Hospital
Full name of responsible person
Dr Shirin Haghighi
Street address
Velenjak St., Shahid Chamran Highway
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Taleghani Hospital- Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. Seyed Ali Aiayee
Street address
Velenjak St., Shahid Chamran Highway
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Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Taleghani Hospital- Shahid Beheshti 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
Taleghani Hospital- Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr Shirin Haghighi
Position
Oncologist
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)
empty
Study Protocol
empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty