

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 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 be evaluated to investigate their response to treatment based on RECIST 1.1 criteria and side effects. Patients will be 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 University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2243 2560

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drshirinhaghighi@sbmu.ac.ir

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.sbm.u.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 treatment 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 neoadjuvant 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
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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Taleghani Hospital- Shahid Beheshti University of Medical Sciences
Full name of responsible person
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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
City
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
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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