

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 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/m<sup>2</sup>) 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

##### Email address

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/m<sup>2</sup>) 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

+98 21 2243 2570  
**Email**  
drshirinhighi@sbm.ac.ir  
**Web page address**

## Person responsible for scientific inquiries

## 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**  
Taleghani Hospital- Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Dr Shirin Haghighi  
**Position**  
Oncologist  
**Other areas of specialty/work**  
**Street address**  
Velenjak St., Shahid Chamran Highway  
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## Person responsible for updating data

#### Contact

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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*