

# The role of an intraoperative intraperitoneal chemotherapy after neoadjuvant chemotherapy in patients with advanced (stage IIIC) epithelial ovarian cancer

<b>Submission date</b> 21/07/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 14/09/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 08/09/2015	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Ovarian cancer is a cancer that begins in an ovary. Intraperitoneal application (injection into the body cavity) of the anti-cancer drug cisplatin prolongs the survival of patients with advanced ovarian cancer when applied after primary surgery. However, due to its side effects this treatment is rarely used. The aim of this study is to determine the effectiveness and side effects of a single intraperitoneal application of cisplatin at surgery after the completion of chemotherapy with paclitaxel and carboplatin in patients with advanced ovarian cancer.

### Who can participate?

Women aged under 75 with advanced (stage IIIC) epithelial ovarian cancer.

### What does the study involve?

Patients are treated with chemotherapy consisting of paclitaxel and carboplatin. After 3-6 cycles of chemotherapy patients undergo surgery. At the end of the surgery all patients will receive a single intraperitoneal application of cisplatin. Any side effects will be recorded daily and later at follow-up visits. After 4-6 weeks the patients will be treated with a further three cycles of paclitaxel/carboplatin. Patients will then be followed up every 3 months.

### What are the possible benefits and risks of participating?

Not provided at time of registration.

### Where is the study run from?

Institute of Oncology Ljubljana (Slovenia).

### When is the study starting and how long is it expected to run for?

February 2015 to December 2018.

Who is funding the study?  
Institute of Oncology Ljubljana (Slovenia).

Who is the main contact?  
Dr Erik Škof

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Erik Skof

**Contact details**  
Institute of Oncology Ljubljana  
Ljubljana  
Slovenia  
1000

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
N/A

## Study information

**Scientific Title**  
The role of a single intraoperative intraperitoneal application of cisplatin after neoadjuvant chemotherapy in patients with advanced (stage IIIC) epithelial ovarian cancer

**Study objectives**  
Single intraoperative intraperitoneal application of cisplatin improves progression free survival (PFS) after neoadjuvant chemotherapy in patients with advanced (stage IIIC) epithelial ovarian cancer.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**  
1. Komisija Republike Slovenije Za Medicinsko Etiko, 16/05/2015, KME 127/04/15  
2. Republic of Slovenia National Medical Ethics Committee, 16/05/2015, NMEC 127/04/15

**Study design**

Prospective phase II trial

**Primary study design**

Interventional

**Secondary study design**

Non randomised study

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

**Health condition(s) or problem(s) studied**

Advanced (stage IIIC) epithelial ovarian cancer

**Interventions**

Patients will start with neoadjuvant chemotherapy (consisting of paclitaxel 175mg/m<sup>2</sup> 3h i.v. infusion and carboplatin AUC 6 1h i.v. infusion). After 3-6 cycles of neoadjuvant chemotherapy patients will undergo surgery (aim is maximal debulking). At the end of surgery all eligible patients will receive a single intraperitoneal infusion of cisplatin 75 mg/m<sup>2</sup>. Potential toxicity of intraperitoneal chemotherapy will be recorded daily and later at follow-up visits. Later (after 4-6 weeks) postoperative (adjuvant) i.v. chemotherapy (3 cycles of paclitaxel/carboplatin) is planned. Thereafter patients will be followed up every 3 months (gin. exam, Ca 125, US/CT at suspected relapse).

**Intervention Type**

Drug

**Phase**

Phase II

**Drug/device/biological/vaccine name(s)**

Cisplatin

**Primary outcome measure**

1. Toxicity (side effects of chemotherapy and of surgery), determined and scored by CTCAE criteria v. 3.0 (renal function, neuropathy, death, etc).
2. Progression-free survival (PFS), estimated using the Kaplan–Meyer method.

Outcomes will be recorded daily after surgery and chemotherapy, and at follow-up every 3 months.

**Secondary outcome measures**

1. Overall survival (OS), estimated using the Kaplan–Meyer method.
2. R0 resection rate (no macroscopic residual disease), provided by surgeon and pathologist reports.

Outcomes will be recorded daily after surgery and chemotherapy, and at follow-up every 3 months.

**Overall study start date**

19/02/2015

**Completion date**

31/12/2018

## **Eligibility**

**Key inclusion criteria**

1. Age <75 years
2. PS 0-1 (WHO)
3. Histology of epithelial ovarian, fallopian tube or primary peritoneal serous cancer
4. Stage IIIC primary inoperable disease
5. Completed neoadjuvant chemotherapy with paclitaxel/carboplatin (min 3 - max 6 cycles)
6. Operable disease after neoadjuvant chemotherapy
7. Normal blood count, kidney and liver biochemistry
8. Surgery planned 4-6 weeks after completion of neoadjuvant chemotherapy
9. Signed informed consent

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Female

**Target number of participants**

100

**Key exclusion criteria**

1. No histology sample available
2. Not proven origin in ovaries, fallopian tubes or peritoneum
3. Stage other than IIIC
4. Primary operable disease
5. No prior neoadjuvant chemotherapy with paclitaxel/carboplatin combination
6. PS 2 or higher (WHO)
7. Progression of disease during neoadjuvant chemotherapy
8. Participation in other study
9. Other prior cancers (except planocelular skin cancer, cervical cancer in situ or breast cancer <5 years after end of treatment)

**Date of first enrolment**

01/09/2015

**Date of final enrolment**

31/12/2018

## **Locations**

### **Countries of recruitment**

Slovenia

### **Study participating centre**

**Institute of Oncology Ljubljana**

Zaloska 2

Ljubljana

Slovenia

1000

## **Sponsor information**

### **Organisation**

Institute of Oncology Ljubljana

### **Sponsor details**

Zaloska 2

Ljubljana

Slovenia

1000

### **Sponsor type**

Hospital/treatment centre

### **Website**

[www.onko-i.si](http://www.onko-i.si)

### **ROR**

<https://ror.org/00y5zsg21>

## **Funder(s)**

### **Funder type**

Hospital/treatment centre

### **Funder Name**

Institute of Oncology Ljubljana (Slovenia)

# Results and Publications

## **Publication and dissemination plan**

Results of this study are planned to be presented at the ESMO and/or ASCO meeting and published in the scientific literature (with SCI impact factor).

## **Intention to publish date**

## **Individual participant data (IPD) sharing plan**

## **IPD sharing plan summary**

Available on request