

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

Submission date 21/07/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 14/09/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 08/09/2015	Condition category 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

Protocol serial number
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

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Advanced (stage IIIC) epithelial ovarian cancer

Interventions

Patients will start with neoadjuvant chemotherapy (consisting of paclitaxel 175mg/m² 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/m². 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(s)

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.

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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

ROR

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

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Institute of Oncology Ljubljana (Slovenia)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request