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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

Registration date
14/09/2015

Overall study status
Completed

Last Edited
08/09/2015

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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 recieve 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 (Solvenia).

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/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 recieve 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 paklitaxel/karboplatin) 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

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