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Long term outcomes in patients with ovarian or abdominal cancer who underwent chemotherapy either before or after surgery to remove the affected areas

Submission date
15/11/2019

Registration date
25/11/2019

Last Edited
30/12/2022

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Ovarian cancer is mostly diagnosed at advanced stage. Better survival is achieved through surgery to completely remove the ovaries followed by chemotherapy. In some cases where surgical removal is difficult and dangerous, chemotherapy is given before surgery to try and reduce the size of the affected area (known as preoperative or neoadjuvant chemotherapy). The study aims to examine the usefulness of preoperative chemotherapy.

Who can participate?
Patients with ovarian and peritoneal cancers accompanied with diaphragmatic lesions who underwent standard surgery combined with diaphragmatic surgery, with or without preoperative chemotherapy, at two related institutions from January 2010 to December 2013

What does the study involve?
Medical records are analysed to assess the cancer recurrence period, recurrence site, and the date of last confirmed survival.

What are the possible benefits and risks of participating?
None

Where is the study run from?
Tokyo Jikei University School of Medicine, Japan

When is the study starting and how long is it expected to run for?
April 2019 to November 2019

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
30-466(9487)

Study information

Scientific Title
Neoadjuvant chemotherapy for patients with diaphragmatic lesions: A prognostic postoperative analysis

Acronym
NAC-DIAL

Study objectives
The aim is to analyse the prognosis of patients who underwent primary debulking surgery (PDS) and those who underwent interval debulking surgery (IDS) following four courses of paclitaxel +

carboplatin (PC) as preoperative (neoadjuvant) chemotherapy to examine the usefulness of preoperative chemotherapy

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/04/2019, Institutional review board of Tokyo Jikei University School of Medicine (3-25-8 Nishi-Shimbashi, Minato-ku Tokyo 105-8461 Japan; +81-3-3433-1111; rinri@jikei.ac.jp), ref: [30-466(9487)]

Study design
Retrospective cohort study

Primary study design
Observational

Secondary study design
Retrospective cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Ovarian or peritoneal cancer

Interventions
Between January 2010 and December 2013, patients with epithelial ovarian and peritoneal cancers accompanied with diaphragmatic lesions underwent standard surgery combined with diaphragmatic surgery at two related institutions.

IDS was performed in patients in whom partial response or greater was achieved with six courses of postoperative PC following PDS or with four courses of PC following NAC; additional four courses of PC were administered following IDS. Furthermore, patients in the NAC group were defined as those in whom complete excision was considered difficult due to a tumour in the right triangular ligament, which was identified after intraperitoneal exploration was performed by surgery rather than based on diagnostic imaging, and those who had residual lesions of the diaphragm on pre-IDS diagnostic imaging and simultaneously underwent surgery of the diaphragm and IDS. Residual tumour was determined based on macroscopic findings by intraperitoneal exploration.

From the medical records, we surveyed the recurrence period, recurrence site, and the date of last confirmed survival, and analysed prognosis.

Intervention Type

Mixed

Primary outcome measure
Survival curve measured using up to date medical records

Secondary outcome measures
1. Overall survival measured using up to date medical records
2. Progression-free survival measured using up to date medical records

Overall study start date
01/04/2019

Completion date
01/11/2019

Eligibility

Key inclusion criteria
1. Aged 20 years or above
2. Female
3. Attended surgery between January 2010 and December 2013

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
45

Total final enrolment
45

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/04/2019

Date of final enrolment
01/11/2019

Locations

Countries of recruitment

Japan

Study participating centre
Tokyo Jikei University School of Medicine
3-25-8 Nishi-Shimbashi
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Sponsor information

Organisation
The Jikei University School of Medicine

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/039ygjf22

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/12/2020

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/05/2020	30/12/2022	Yes	No