# 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	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
15/11/2019		Protocol		
Registration date 25/11/2019	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	Individual participant data		
30/12/2022	Cancer			

### 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? Motoaki Saito smotoaki@jikei.ac.jp

## Contact information

## Type(s)

Scientific

#### Contact name

Mr Motoaki Saito

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## Additional identifiers

## Clinical Trials Information System (CTIS)

Nil known

## ClinicalTrials.gov (NCT)

Nil known

#### Protocol serial number

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

### Study type(s)

Treatment

## 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(s)

Survival curve measured using up to date medical records

## Key secondary outcome(s))

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

## 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** 

## Healthy volunteers allowed

No

#### Age group

Adult

#### Sex

Female

## 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 Minato-ku Tokyo Japan 105-8461

# Sponsor information

## Organisation

The Jikei University School of Medicine

#### **ROR**

https://ror.org/039ygjf22

# Funder(s)

## Funder type

Other

#### Funder Name

Investigator initiated and funded

## **Results and Publications**

## 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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes