

# Is it beneficial to give chemotherapy before surgery in patients with advanced ovarian cancer?

<b>Submission date</b> 29/09/2020	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 02/10/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 08/10/2020	<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, or cancer of the ovaries, is one of the most common types of cancer in women. The ovaries are a pair of small organs located low in the tummy that are connected to the womb and store a woman's supply of eggs.

Ovarian cancer mainly affects women who have been through the menopause (usually over the age of 50), but it can sometimes affect younger women.

This is a study on female patients diagnosed with advanced-stage ovarian cancer. The main aim of the study was to compare 2 different treatment strategies: Either undergo surgery first or undergo surgery after receiving chemotherapy first.

### Who can participate?

Patients with locally advanced epithelial ovarian cancer

### What does the study involve?

Patients who are suitable for immediate surgery have surgery to remove the tumor followed by chemotherapy for 10 weeks. Those not suitable for surgery have 10 weeks of chemotherapy followed by surgery. Follow up is for 18 months.

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

Possible benefits from participating include surgical excision of ovarian cancer with the intent of cure. Possible risks of participating include the occurrence of complications after surgery as bleeding and infection. The group that will receive chemotherapy first may encounter complications as nausea, vomiting and hair loss.

### Where is the study run from?

The National Cancer Institute, Cairo University (Egypt)

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

September 2017 to July 2019

Who is funding the study?  
The National Cancer Institute, Cairo University (Egypt)

Who is the main contact?  
Dr Tamer Manie, tamer.manie@nci.cu.edu.eg

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**Clinical Trials Information System (CTIS)**  
Nil known

**ClinicalTrials.gov (NCT)**  
Nil known

**Protocol serial number**  
201617040.3

## Study information

**Scientific Title**  
Is interval debulking surgery as effective as primary debulking surgery for locally advanced epithelial ovarian cancer?

**Acronym**  
IIDSAEAPDSFLAEOC

**Study objectives**  
Interval debulking surgery after neoadjuvant chemotherapy is not inferior to primary debulking surgery in locally advanced epithelial ovarian cancer

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Approved 17/10/2017, Cairo University National Cancer Institute IRB (Fom El Khalig, Cairo, 11796, Egypt; +(202) 25328286; irb@nci.cu.edu.eg), ref: n/a

## **Study design**

Single center observational prospective cohort study

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

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

Ovarian cancer

## **Interventions**

Patients in the primary debulking surgery arm underwent surgical exploration with the intent of having no residual tumor. The surgical procedure included total abdominal hysterectomy, bilateral salpingo-oophorectomy, omentectomy, pelvic and/or para-aortic lymphadenectomy and resection of parts of adjacent organs if needed to achieve complete cytoreduction.

This was followed by 6 cycles of adjuvant chemotherapy every 3 weeks.

Patients who were not considered good surgical candidates or whose tumors were deemed irresectable received 6 cycles of neoadjuvant chemotherapy every 3 weeks followed by surgical exploration as the primary debulking surgery arm.

Total duration of treatment 10 weeks and 18 months follow up.

## **Intervention Type**

Procedure/Surgery

## **Primary outcome(s)**

Retrieved from operative notes in patient medical records at the end of patient stay:

1. Operative time
2. Procedure performed
3. Need for blood transfusion
4. Post operative complications

## **Key secondary outcome(s)**

Progression free survival assessed using imaging and lab tests every 6 months up to 18 months

## **Completion date**

31/07/2019

## **Eligibility**

### **Key inclusion criteria**

Patients with locally advanced epithelial ovarian cancer

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

Female

**Total final enrolment**

56

**Key exclusion criteria**

1. Patients with stage I and II tumors
2. Non-epithelial histology or borderline tumors
3. Underwent surgical interventions outside the trial institute

**Date of first enrolment**

17/10/2017

**Date of final enrolment**

31/01/2019

## **Locations**

**Countries of recruitment**

Egypt

**Study participating centre**

**National Cancer Institute**

Fom El Khalig street

Cairo

Egypt

11796

## **Sponsor information**

**Organisation**

Cairo University

ROR

<https://ror.org/03q21mh05>

## Funder(s)

### Funder type

University/education

### Funder Name

National Cancer Institute, Cairo University

### Alternative Name(s)

NCI

### Funding Body Type

Government organisation

### Funding Body Subtype

National government

### Location

Egypt

## 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

Other

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol file</a>			08/10/2020	No	No