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

Submission date 29/09/2020	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 02/10/2020	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 08/10/2020	**Condition category** Cancer	[_] Individual participant data [_] 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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Non randomised 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 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-ophorectomy , 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 measure
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

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

Overall study start date
15/09/2017

Completion date
31/07/2019

Eligibility

Key inclusion criteria
Patients with locally advanced epithelial ovarian cancer

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
50

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

Sponsor details
National Cancer Institute
Kasr Al Eini street
Fom El Khalig
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11796
+20 23689711
webmaster@nci.cu.edu.eg

Sponsor type
Hospital/treatment centre

Website
https://nci.cu.edu.eg

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

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

Intention to publish date
15/11/2020

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
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			08/10/2020	No	No