SHANGHAI GYNECOLOGIC ONCOLOGY GROUP
上海妇科肿瘤协作组

GYNECOLOGIC CANCER INTERGROUP
An Organization of International Cooperative Groups for Clinical Trials in Gynecologic Cancers

The Asia SUNNY Study (SGOG OV 4B)

Study of Upfront Surgery versus Neoadjuvant Chemotherapy Followed by Interval Debulking Surgery for Patients with Stage IIIC and IV Ovarian Cancer

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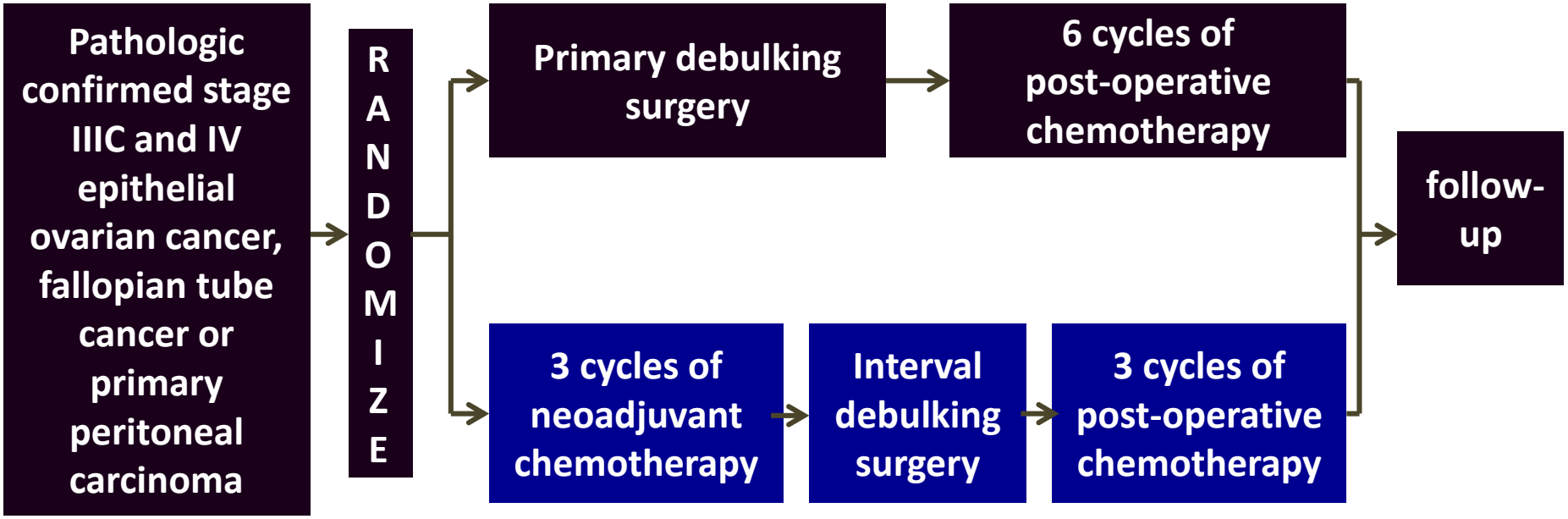

Primary endpoint

- OS

Secondary endpoints

- PFS
- 30-day post-operative complications
- QOL (surgical times, non-treatment intervals…)

Open: Nov. 2015
Closed: Nov. 2020
Target accrual: 456

Inclusion criteria

- Women aged ≥ 18 years.
- Pathologic confirmed stage IIIC and IV epithelial ovarian cancer, fallopian tube cancer or primary peritoneal carcinoma (diagnosed by biopsy or fine needle aspiration*).

  Laparoscopic biopsy with pictures is recommended.

  – * If fine needle aspiration showing an adenocarcinoma, patients should satisfy the following conditions:

    a. *the patient has a pelvic mass, and*

    b. omental cake or other metastasis larger than 2 cm in the upper abdomen, or pathologic confirmed extra-abdominal metastasis, and

    c. serum CA125/CEA ratio>25. And serum CA199 is recommeded.

    d. If serum CA125/CEA ratio<25 or malignancies of other origins, such as breasts and digestive tract, are suspected from symptoms, physical examinations or imaging diagnosis, endoscopy or ultrasonography should be done to exclusive metastasis ovarian cancer.

Inclusion criteria

- ECOG performance status of 0 to 2.
- ASA score of 1 to 2.
- Adequate bone marrow, liver and renal function to receive chemotherapy and subsequently to undergo surgery:
  - white blood cells >3,000/µL, absolute neutrophil count ≥1,500/µL, platelets ≥100,000/µL, hemoglobin ≥9 g/dL
  - serum creatinine <1.25 x upper normal limit (UNL) or creatinine clearance ≥60 mL/min according to Cockroft-Gault formula or to local lab measurement
  - serum bilirubin <1.25 x UNL, AST(SGOT) and ALT(SGPT) <2.5 x UNL.
- Comply with the study protocol and follow-up.
- Written informed consent.

Exclusion criteria

- Patients with non-epithelial tumors as well as borderline tumors.
- Mucinous ovarian cancer.
- Synchronous or metachronous malignancy within 5 years other than carcinoma in situ.
- Any other concurrent medical conditions contraindicating surgery or chemotherapy that could compromise the adherence to the protocol.
- Other conditions, such as religious, psychological and other factors, that could interfere with provision of informed consent, compliance to study procedures, or follow-up.

Stratification (1)

• Institution	8601, 8602,… 8201,8202,…
• Method of biopsy	☐laparoscopy ☐FNA
• FIGO Stage	☐IIIC ☐IV
• Age	☐≥70 years ☐<70 years
• Extensive metastasis diseases* in the upper abdomen	☐Yes ☐No

* defined as carcinomatosis or the number of lesions ≥ 3 in the upper abdomen

Stratification (2)

IP chemotherapy

- The primary results of the SGOG OV1 IP trial (NCT01669226): an additional intraperitoneal cisplatin and etoposide was the winner when compared to standard chemo

Surgery (1)

- Aim: Maximal cytoreduction in each group.
- 50% R0
- UAD documented, as well as the procedures performed in cytoreduction.
- It is recommended to take pictures by Laparoscopic diagnosis

Surgery (2)

- (NACT+) ICR is performed,
  - 1) if there is no visible lesion in the peritoneum of the pelvic, paracolic sulcus or diaphragm, there is no need to resect the peritoneum; however, if there are any suspected visible lesions after NACT, the involved peritoneum before NACT based on the findinds by laparoscopy should be resected;
  - 2) **Intestine mesenterium**: resection or coagulation is recommended if there is any visible lesion;
  - 3) bowel resection or splenectomy is not **compulsory** except when complete resection is possibly obtained by these procedures.

Endpoints

- **Primary endpoint**
  - Overall survival
- **Secondary endpoints**
  - Progression-free survival
  - 30-day post-operative complications
  - Quality of life assessments (QLQ-C30, FACT-O): baseline; 3th cycle of intravenous chemotherapy; 1 and 6 months after first-line chemotherapy.

Sample size

- **Hypothesis： Upfront radical surgery enhance the survivorship when compared with upfront chemo**

- Accrual target: **456** subjects
  - at a 1:1 ratio
  - accrual time of 5 years
  - a minimum follow-up of 2 years
  - assuming a hazard ratio of **0.6803**
  - α 0.05, power 90%

Randomization

Website Address： http://iwrs.fudan.edu.cn/shmc-1.0.0/login.html

- Username and password is necessary
- Different accounts in different institutions
- Change the default password after login

Study timelines

Study stage	Milestone	Date(act/plan)
Set-up	Protocol approved	**Nov.30 2015**
	First center initiated -**Zhongshan Hospital, Fudan University**	Dec. 2015
	Last center initiated -**KGOG**	Aug. 2016
Recruitment	First subject first visit	Dec.9 2015
	Last subject first visit	Dec.10 2020
Data management	Last subject last visit -Overall survival	**Dec.10 2022**
Analysis	Statistical analysis complete	Mar.10 2023
Report	Approval of study report	Feb.10 2024

Expected accrual: 8 pts. per mos. (7-9)

Grants

Local grant for Dr Rongyu Zang, 2015-2018

Another grant for Dr Jianqing Zhu estimates approved on July 2016

THANK YOU!