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# Upfront debulking surgery versus neoadjuvant chemotherapy in ovarian cancer

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 23/04/2010 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 23/04/2010 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 19/10/2018 | Cancer | |

**Plain English summary of protocol**
Not provided at time of registration

**Study website**
http://www.eortc.be/protoc/Details.asp?Protocol=55971

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
921; EORTC 55971

# Study information

## Scientific Title
Randomised phase III study comparing upfront debulking surgery versus neo-adjuvant chemotherapy in patients with epithelial ovarian carcinoma

## Study objectives
This is a randomised phase III study comparing upfront debulking surgery versus neo-adjuvant chemotherapy in patients with Stage IIIc or IV epithelial ovarian carcinoma.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
North West MREC approved on the 18th February 2000 (ref: 99/8/73). All other centres will seek ethics approval before recruiting participants.

## Study design
Randomised interventional treatment trial

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
GP practice

## Study type(s)
Treatment

## Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

## Health condition(s) or problem(s) studied
Topic: National Cancer Research Network; Subtopic: Gynaecological Cancer; Disease: Ovary

## Interventions
Arm A: upfront maximal cytoreductive surgery -
3 courses of platinum-containing chemo (3-weekly):
1. Paclitaxel 135 mg/m^2 (over 24 hours) then cisplatin 75 mg/m^2, or
2. Paclitaxel 175 mg/m^2 (over 3 hours) then cisplatin 75 mg/m^2, or
3. Paclitaxel 175 mg/m^2 (over 3 hours) then carboplatin AUC 5
Interval debulking if initial surgery was not optimal. 3 courses of platinum-containing chemotherapy (as above) and 2nd look surgery is allowed.

Arm B: no upfront maximal cytoreductive surgery -
3 courses of platinum-containing chemo (3-weekly):

1. Paclitaxel 135 mg/m^2 (over 24 hours) then cisplatin 75 mg/m^2, or
2. Paclitaxel 175 mg/m^2 (over 3 hours) then cisplatin 75 mg/m^2, or
3. Paclitaxel 175 mg/m^2 (over 3 hours) then carboplatin AUC 5
Interval debulking surgery. 3 courses platinum-containing chemotherapy (as above) and 2nd look surgery is allowed.

Follow-up every 3 months the first 2 years; every 6 months year 3 - 5; yearly afterwards.

Computed tomography (CT) scans were performed at screening, after cycle 3, after interval debulk (if perfomed) and after cycle 6. Progression defined according to Response Evaluation Criteria in Solid Tumours (RECIST) guidelines for CT or clinical signs/symptoms on physical examination during follow-up.

CA-125 tumour markers were measured at screening, before each cycle and at every follow-up visit. Progression on rising CA-125 (criteria in protocol). Time to progression will be defined as the time to clinically, CA125 or surgically defined PD, whichever occurs first. Overall survival is defined as the time from randomisation to the time of death of any cause. Overall survival will be censored at the last follow-up assessment at which the patient was known to be alive.

### Intervention Type
Other

### Phase
Phase III

### Primary outcome measure
Overall crude survival

### Secondary outcome measures
1. Progression-free survival
2. Quality of life according to the EORTC questionnaire QLQ-C30
3. To assess the different treatment complications in relation to treatment arm

### Overall study start date
21/09/1998

### Completion date
06/12/2006

## Eligibility

### Key inclusion criteria
1. Histologically proven stage IIIC or IV ovarian epithelial carcinoma, peritoneal carcinoma, or fallopian tube carcinoma
2. If biopsy is not available, evidence of adenocarcinoma by fine needle aspiration allowed if all of the following are true:
2.1. Presence of pelvic ovarian mass
2.2. Omental cake or other metastasis larger than 2 cm in the upper abdomen and/or regional lymph node metastasis
2.3. CA 125/carcinoembryonic antigen ratio greater than 25 (if ratio less than 25, barium enema or colonoscopy AND gastroscopy or radiological examination of the stomach must be negative

for primary tumor)
2.4. Normal mammography (if CA 125/carcinoembryonic antigen ratio less than 25)
3. Tumor greater than 2 cm, excluding ovaries, on laparoscopy or CT scan
4. No brain or leptomeningeal metastases
5. No other prior procedures except diagnostic biopsy by laparotomy or laparoscopy
6. Performance status: World Health Organisation (WHO) performance status 0 - 2
7. WBC greater than 3,000/mm3
8. Platelet count greater than 100,000/mm3
9. Bilirubin less than 1.25 times upper limit of normal (ULN)
10. Creatinine less than 1.25 times ULN
11. No other serious disabling diseases contraindicating primary cytoreductive surgery or primary platin-based chemotherapy
12. No other prior primary malignancies except carcinoma in situ of the cervix or basal cell carcinoma of the skin
13. No psychological, familial, sociological, or geographical condition potentially preventing protocol compliance or follow-up
14. Aged between 18 - 50 years

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Female

### Target number of participants
Planned Sample Size: 720; UK Sample Size: 65

### Key exclusion criteria
1. No other serious disabling diseases contraindicating for primary cytoreductive surgery or primary platin based chemotherapy
2. No other prior primary malignancies, except for carcinoma in situ of the cervix and basal carcinoma of the skin
3. Absence of any psychological, familial, sociological or geographical condition potentially preventing compliance with the study protocol and follow-up schedule

### Date of first enrolment
21/09/1998

### Date of final enrolment
06/12/2006

## Locations

### Countries of recruitment

Argentina

Austria

Belgium

Canada

Denmark

England

France

Germany

Ireland

Italy

Netherlands

Norway

Portugal

Spain

Sweden

United Kingdom

### Study participating centre
### Department of Medical Oncology
Northwood
United Kingdom
HA6 2RN

# Sponsor information

### Organisation
European Organisation for Research and Treatment of Cancer (EORTC) (Belgium)

### Sponsor details

Avenue Mounierlaan, 83/11
Brussels
Belgium
1200

**Sponsor type**
Research organisation

**Website**
http://www.eortc.be/

**ROR**
https://ror.org/034wxcc35

# Funder(s)

**Funder type**
Government

**Funder Name**
European Organisation for Research and Treatment of Cancer (EORTC) (Belgium)

# Results and Publications

**Publication and dissemination plan**
Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not provided at time of registration

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Plain English results | | | | No | Yes |
| Results article | results | 01/01/2008 | | Yes | No |