

Upfront debulking surgery versus neoadjuvant chemotherapy in ovarian cancer

Submission date 23/04/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/04/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 19/10/2018	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr Gavin Shreeves

Contact details
Department of Medical Oncology
Rickmansworth Road
Northwood
United Kingdom
HA6 2RN

Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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/m² (over 24 hours) then cisplatin 75 mg/m², or
2. Paclitaxel 175 mg/m² (over 3 hours) then cisplatin 75 mg/m², or
3. Paclitaxel 175 mg/m² (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/m² (over 24 hours) then cisplatin 75 mg/m², or
2. Paclitaxel 175 mg/m² (over 3 hours) then cisplatin 75 mg/m², or
3. Paclitaxel 175 mg/m² (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 performed) 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(s)

Overall crude survival

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Female

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**

United Kingdom

England

Argentina

Austria

Belgium

Canada

Denmark

France

Germany

Ireland

Italy

Netherlands

Norway

Portugal

Spain

Sweden

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)

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

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?
Results article	results	01/01/2008		Yes	No
Plain English results				No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes