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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