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To compare the Efficacy of additional Tumor DebulKing Surgery versus chemotherapy alone in recurrent Platinum-sensitive Ovarian cancer

Submission date
24/05/2011

Recruitment status
No longer recruiting

Registration date
04/08/2011

Overall study status
Completed

Last Edited
01/07/2021

Condition category
Cancer

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/a-trial-looking-surgery-ovarian-cancer-that-come-back-desktop-3

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT01166737

Secondary identifying numbers
AGO-OVAR-ID:AGO-OVAR OP.4 (DESKTOP III)

Study information

Scientific Title
A randomised multicentre study to compare the Efficacy of additional Tumor DebulKing Surgery versus chemotherapy alone in recurrent Platinum-sensitive Ovarian cancer

Acronym
DESKTOP III

Study objectives
The hypothesis H0: "no difference in the survival probability between treatment groups at any time" will be tested against the alternative H1: "difference in survival probability between groups".

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval pending as of 25/05/2011

Study design
Open label prospective randomised multicentre study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
Ovarian Cancer

Interventions
DESKTOP III is a surgery based trial and does not involve any Investigational medicinal products (IMPs):

Patients will be randomised into one of two treatment groups:

Group A: Surgery (with the aim of complete tumour removal) followed by chemotherapy. The extent of surgery in Group A is difficult to estimate beforehand as it depends how much the tumour has spread. However, the aim is complete tumour removal. These tumours can spread into the whole abdominal cavity, the peritoneum, the intestine, the organs of the upper abdomen and also into the lymph nodes. Secondary surgery may therefore include the removal of these affected parts or further actions if it is an extensive tumour. Patients randomised to Group A, will recover from surgery and will receive chemotherapy. After surgery, patients in Group A will receive the normal treatment and care under the attending doctor.

Group B: Chemotherapy only. Patients in Group B will have their treatment and care carried out as normal (as if they weren't in the trial) under the medical care of their attending doctor. For Group B patients, if after chemotherapy it is thought that they may still benefit from surgery, this will certainly be possible.

Patients will be interviewed 60 days after the start of the treatment and then followed up by a doctor. The follow up process will be quarterly for 2 years, 6 monthly for 5 years and then annually.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Overall survival (OS) in patients with platinum-sensitive recurrent ovarian cancer with a positive AGO-score randomized to cytoreductive surgery followed by chemotherapy of the physician's choice versus chemotherapy of the physician's choice alone (recommended: platinum combination therapy). Overall survival is defined as the interval between date of randomisation and date of death.

Secondary outcome measures
1. Quality of Life at baseline, 6, and 12 months after randomization assessed by EORTC QLQ 30 and FACT NCCN Ovarian Symptom Index (if available in the language of the participating centre).
2. Progression-free-survival in treatment groups. Progression free survival is defined as interval between date of randomisation and 2nd relapse/progression or death (whatever occurs first). Tumor progression is defined as progressive disease according to Response Evaluation Criteria In Solid Tumors (RECIST) or Gynecologic Cancer Intergroup (GCIG) criteria or death without progression or clinical deterioration of performance status with associated signs of disease (e.g. bowel obstruction and non-measurable disease).
3. Rate of complete resection as prognostic factor
4. Complication rate associated with surgery until definitive hospital discharge (Reattendance within 1 week for surgical complications counts as one hospital stay).
5. Exploratory analysis of surgical characteristics and applied chemotherapy
6. Predictive and prognostic value of cancer antigen-125 (CA-125)

Overall study start date
01/10/2011

Completion date
01/10/2017

Eligibility

Key inclusion criteria
1. Patients with first recurrence of platinum sensitive, invasive epithelial ovarian-, fallopian tube- or primary peritoneal cancer of any initial stage
2. Progression-free interval of at least 6 months after end of last platinum-containing therapy, or recurrence within 6 months or later after primary surgery if the patient has not received prior chemotherapy in patients with International Federation of Gynecology and Obstetrics (FIGO) stage I. Non cytostatic maintenance therapy not containing platinum will not be considered for this calculation
3. A positive AGO-score. Obligatory requirements for a positive AGO recurrence score in platinum-sensitive disease: Performance status Eastern Cooperative Oncology Group (ECOG) 0. No residual tumor after primary surgery (if unknown, alternatively primary FIGO stage I / II). If report from 1st surgery is not available contact study chairman who will decide whether inclusion is possible or not. Absence of ascites (cut off < 500 ml: radiological or ultrasound estimation).
4. Women aged more than or equal to 18 years
5. Complete resection of the tumor by median laparotomy seems possible (estimated by an experienced surgeon). Intra-abdominal disease has to be excluded by magetic resonance imaging (MRI) / computerised tomography (CT) if other surgical approaches for isolated extra-abdominal recurrences are planned
6. Patients who have given their signed and written informed consent and their consent to data transmission and -processing

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
408

Total final enrolment
407

Key exclusion criteria
1. Patients with non-epithelial tumors as well as borderline tumors
2. Patients without recurrence who are scheduled for diagnostic/second-look surgery or debulking surgery after completion of chemotherapy
3. More than one prior chemotherapy

4. Patients with second, third, or later recurrence
5. Patients with second malignancies who have been treated by laparotomy, as well as other neoplasms, if the treatment might interfere with the treatment of relapsed ovarian cancer or if major impact on prognosis is expected
6. Patients with so-called platinum-refractory tumor, i.e. progression during chemotherapy or recurrence within 6 months after end of former first platinum containing therapy
7. Only palliative surgery planned
8. Radiological signs suggesting metastases not accessible to surgical removal (i.e. complete resection is deemed impossible)
9. Any concomitant disease not allowing surgery and / or chemotherapy
10. Any medical history indicating excessive peri-operative risk
11. Any current medication inducing considerable surgical risk (e.g. bleeding: due to oral anticoagulating agents, bevacizumab)

Date of first enrolment
01/10/2011

Date of final enrolment
01/10/2014

Locations

Countries of recruitment
England

Germany

United Kingdom

Study participating centre
City Hospital
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Sponsor information

Organisation
AGO Research GmbH (Germany)

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Sponsor type
Industry

Website
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ROR
https://ror.org/01jdhsq12

Funder(s)

Funder type
Charity

Funder Name
Clinical Trials Awards and Advisory Committee (CTAAC) (UK)

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?
Abstract results	results presented at ASCO	20/05/2017	15/04/2019	No	No
Plain English results			01/07/2021	No	Yes