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A randomised feasibility trial to determine the impact of timing of surgery and chemotherapy in newly diagnosed patients with advanced epithelial ovarian, primary peritoneal, or fallopian tube carcinoma

Submission date
23/11/2005

Recruitment status
No longer recruiting

Registration date
25/01/2006

Overall study status
Completed

Last Edited
26/10/2022

Condition category
Cancer

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

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-comparing-surgery-before-and-during-chemotherapy-for-ovarian-fallopian-tube-or-primary-peritoneal-cancer

Study website
http://www.ctu.mrc.ac.uk/studies/CHORUS.asp

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00075712

Secondary identifying numbers
N/A

Study information

Scientific Title
A randomised feasibility trial to determine the impact of timing of surgery and chemotherapy in newly diagnosed patients with advanced epithelial ovarian, primary peritoneal, or fallopian tube carcinoma

Acronym
CHORUS

Study objectives
The aim of this trial is to assess the acceptability of this randomised trial to clinicians and patients. It is intended that between 100 and 150 patients be randomised over a period of 18 months. If this is achieved, a large phase III trial is planned to follow on from this feasibility trial. The aim of the phase III trial is to determine the impact of the timing of surgery and chemotherapy in patients with advanced epithelial ovarian, primary peritoneal, or fallopian tube cancer, in terms of survival, progression-free survival, and quality of life.

More details can be found at: http://www.ctu.mrc.ac.uk/research_areas/study_details.aspx?s=9

Ethics approval required
Old ethics approval format

Ethics approval(s)
Metropolitan Multi-centre Research Ethics Committee, 22/09/2003, ref: MREC03/11/058

Study design
Two-arm multi-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Patient information leaflet on page 22 of the protocol: http://www.ctu.mrc.ac.uk/studies/documents/protocol.pdf

Health condition(s) or problem(s) studied
Advanced epithelial ovarian, primary peritoneal or fallopian tube carcinoma

Interventions
Primary surgery arm (control):
This comprises radical surgery followed by 6 cycles of carboplatin-based chemotherapy at 3-weekly intervals. The interval between randomisation and the initiation of surgery should be a maximum of 4 weeks. Chemotherapy should commence within 6 weeks of primary surgery. Interval debulking surgery may be carried out at the discretion of the clinician if appropriate and if stated as the intention prior to randomisation; this should be carried out as close as possible to 3 weeks after the 3rd cycle of chemotherapy. Chemotherapy should be resumed within 6 weeks of interval debulking surgery.

Neoadjuvant chemotherapy arm:
This comprises histological or cytological confirmation of disease followed by 3 cycles of carboplatin-based chemotherapy at 3-weekly intervals. Neoadjuvant chemotherapy should be carried out within 4 weeks of randomisation. Surgery following neoadjuvant chemotherapy to be performed as close as possible to 3 weeks after the 3rd cycle of chemotherapy. A further 3 cycles of carboplatin-based chemotherapy should be given within 6 weeks of surgery.

Doses of chemotherapy regimens:
Paclitaxel and carboplatin combination:
Paclitaxel 175 mg/m2, Carboplatin 5 x (51Cr-EDTA or measured clearance + 25) mg or 6 x (calculated clearance + 25) mg repeated every 3 weeks for 6 cycles
Carboplatin as a single agent:
Carboplatin 6 x (51Cr-EDTA or measured clearance + 25) mg or 7 x (calculated clearance + 25) mg
The chemotherapy regimens chosen were based on results from the ICON3 trial.

Intervention Type
Mixed

Primary outcome measure
Overall survival

Secondary outcome measures
1. Progression-free survival
2. Quality of life

Overall study start date
01/03/2004

Completion date
30/08/2010

Eligibility

Key inclusion criteria
1. Clinical and imaging evidence of a pelvic mass with extrapelvic metastatic disease at presentation
2. Randomisation should be carried out within 4 weeks of obtaining clinical and imaging evidence of disease
3. Serum Cancer Antigen (CA 125) / CarcinoEmbryonic Antigen (CEA) ratio >25 (if the serum CA 125/CEA is less than or equal to 25 and the serum CEA is above the upper limit of normal, the patient should undergo investigations to exclude gastrointestinal cancer)
4. Patient planned to receive carboplatin-based chemotherapy
5. Patient fit to undergo protocol treatment and follow-up
6. No concomitant or previous malignancy likely to interfere with protocol treatments or comparisons
7. Written informed consent of the patient

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
100-150

Total final enrolment
550

Key exclusion criteria
N/A

Date of first enrolment
01/03/2004

Date of final enrolment
30/08/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Nuffield Dept of Obstetrics and Gynaecology
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Sponsor information

Organisation
Medical Research Council (UK)

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Sponsor type
Research council

ROR
https://ror.org/03x94j517

Funder(s)

Funder type
Research council

Funder Name
Start up grant from Royal College of Obstetricians and Gynaecologists (RCOG; UK)

Funder Name
Core funding from Medical Research Council Clinical Trials Unit (MRC CTU; UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

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	18/07/2015		Yes	No
Plain English results			26/10/2022	No	Yes