

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 25/01/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 26/10/2022	Condition category Cancer	<input type="checkbox"/> 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>

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT00075712

Protocol serial number

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

Study type(s)

Treatment

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(s)

Overall survival

Key secondary outcome(s)

1. Progression-free survival
2. Quality of life

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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**

United Kingdom

England

Study participating centre

Nuffield Dept of Obstetrics and Gynaecology

Oxford

United Kingdom

OX3 9DU

Sponsor information**Organisation**

Medical Research Council (UK)

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

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Plain English results			26/10/2022	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes