

# 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

<b>Submission date</b> 23/11/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 25/01/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 26/10/2022	<b>Condition category</b> 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>

## Study website

<http://www.ctu.mrc.ac.uk/studies/CHORUS.asp>

## Contact information

### Type(s)

Scientific

### Contact name

Prof Sean Kehoe

### Contact details

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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](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/m<sup>2</sup>, 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**  
Oxford  
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## **Sponsor information**

### **Organisation**

Medical Research Council (UK)

### **Sponsor details**

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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?
<a href="#">Results article</a>	results	18/07/2015		Yes	No
<a href="#">Plain English results</a>			26/10/2022	No	Yes