

# A GCIG Intergroup multicentre factorial trial of open label carboplatin and paclitaxel +/- bevacizumab compared with oxaliplatin and capecitabine +/- bevacizumab as first line chemotherapy in patients with mucinous Epithelial Ovarian Cancer

|                                        |                                                   |                                                                                                   |
|----------------------------------------|---------------------------------------------------|---------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>15/07/2008   | <b>Recruitment status</b><br>No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol |
| <b>Registration date</b><br>30/07/2008 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>25/04/2019       | <b>Condition category</b><br>Cancer               | <input type="checkbox"/> Individual participant data                                              |

## Plain English summary of protocol

<http://www.cancerhelp.org.uk/trials/a-trial-chemotherapy-bevacizumab-mucinous-ovarian-cancer-meoc>

## Contact information

### Type(s)

Scientific

### Contact name

Prof Martin Gore

### Contact details

Department of Medicine  
Royal Marsden Hospital  
Fulham Road  
London  
United Kingdom  
SW3 6JJ

-

Martin.Gore@rmh.nhs.uk

## Additional identifiers

**ClinicalTrials.gov (NCT)**

NCT01081262

**Clinical Trials Information System (CTIS)**

2008-000837-23

**Protocol serial number**

UCL/07/095

## **Study information**

### **Scientific Title**

A GCIIG Intergroup multicentre factorial trial of open label carboplatin and paclitaxel +/- bevacizumab compared with oxaliplatin and capecitabine +/- bevacizumab as first line chemotherapy in patients with mucinous Epithelial Ovarian Cancer (mEOC)

### **Acronym**

mEOC

### **Study objectives**

Current hypothesis as of 08/03/2011:

This trial aims to determine whether a combination of oxaliplatin + capecitabine improves overall survival compared to conventional treatment with carboplatin + paclitaxel in patients with advanced mucinous carcinoma of the ovary, and to determine if the addition of bevacizumab improves the overall survival of patients.

The two chemotherapy regimens will also be compared in terms of:

1. Progression free survival
2. Response rate
3. Toxicity
4. Quality of life

Previous hypothesis:

This trial aims to determine whether a combination of oxaliplatin + capecitabine improves overall survival compared to conventional treatment with carboplatin + paclitaxel in patients with advanced mucinous carcinoma of the ovary.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

North West London Research Ethics Committee 2, 29/10/2008, ref: 08/H0720/106

### **Primary study design**

Interventional

### **Study design**

Phase III multicentre randomised controlled trial

### **Study type(s)**

## Treatment

### Health condition(s) or problem(s) studied

Mucinous carcinoma of the ovary

### Interventions

This is a phase III, multicentre, randomised controlled trial. This trial is not blinded due to different timings of administration of drugs between treatment arms.

Control arm: 6 cycles of chemotherapy with the following:

1. Carboplatin AUC 5 or AUC 6, intravenous (IV), given on day 1 (dose depends on method used to measure/ estimate glomerular filtration rate [GFR])
2. Paclitaxel 175 mg/m<sup>2</sup>, IV, given on day 1

Research arm: 6 cycles of chemotherapy with the following:

1. Oxaliplatin 130 mg/m<sup>2</sup>, IV, given on day 1
2. Capecitabine 850 mg/m<sup>2</sup> given twice per day, oral tablets, on the first 14 days of every 21 day cycle (total daily dose 1,700 mg/m<sup>2</sup>)

Added 08/03/2011:

Bevacizumab 15 mg/kg IV given every 3 weeks for 5 or 6 cycles of chemotherapy. Followed by 12 cycles of Bevacizumab along given on day 1 every 3 weeks.

The total duration of follow-up is 5 years. Patients are seen every 3 months in years 1 and 2, and every 6 months in years 3-5. Computerised tomography (CT) or magnetic resonance imaging (MRI) scans are carried out 5 times in Year 1, every 6 months in year 2, and annually in years 3-5.

Previous interventions:

The total duration of follow-up is 5 years. Patients are seen every 3 months in years 1 and 2, and every 6 months in years 3-5. Computerised tomography (CT) or magnetic resonance imaging (MRI) scans are carried out every 6 months in years 1 and 2, and annually in years 3-5.

### Intervention Type

Drug

### Phase

Phase III

### Drug/device/biological/vaccine name(s)

Oxaliplatin, capecitabine, carboplatin, paclitaxel

### Primary outcome(s)

Overall survival. Total duration of follow-up: 5 years.

### Key secondary outcome(s)

1. Progression free survival. Total duration of follow-up: 5 years.
2. Response rate. Total duration of follow-up: 5 years.
3. Toxicity. Total duration of follow-up: 5 years.
4. Quality of life, measured using the Functional Assessment of Cancer Therapy - Ovarian module (FACT-O) at baseline, after the third cycle of chemotherapy, 1 month after the final cycle of chemotherapy, then every 6 months throughout the five year follow-up period

**Completion date**

01/12/2014

## Eligibility

**Key inclusion criteria**

1. Females, age >18 years
2. Histologically confirmed diagnosis of mucinous carcinoma of the ovary or fallopian tube
3. Federation of Obstetricians and Gynaecologists (FIGO) stage II-IV disease (no brain metastases)
4. Recurrent stage I disease (chemonaïve)
5. World Health Organization (WHO)-Eastern Cooperative Oncology Group (ECOG) performance status 0-2
6. Life expectancy >3 months
7. Adequate bone marrow function
8. Adequate hepatic function
9. Adequate renal function
10. Adequate neurological function (sensory and motor neuropathy = grade 1, Common Terminology Criteria for Adverse Events [CTCAE] v4.0)
11. No previous chemotherapy
12. No evidence of primary carcinoma of the upper gastrointestinal tract
13. Patients who have signed an informed consent form
14. Adequate contraceptive precautions if relevant

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Female

**Total final enrolment**

50

**Key exclusion criteria**

1. Histological epithelial non-mucinous cell types
2. Primary peritoneal carcinoma
3. Epithelial ovarian tumours of low malignant potential
4. Previous history of malignancy except cervical carcinoma in situ, and basal cell carcinoma of the skin
5. Presence of known brain metastases
6. Medical or psychiatric conditions that compromise the patient's ability to give informed

consent

7. Concurrent uncontrolled medical conditions

8. Previous chemotherapy, radiotherapy, or any investigational treatment for ovarian or rectal cancer

9. Pregnancy or breastfeeding

10. Clinically significant cardiac disease, symptomatic coronary artery disease and cardiac arrhythmia or myocardial infarction in the last 12 months

11. Patients with any symptoms or history of peripheral neuropathy

12. Previous history of malabsorption or other conditions preventing oral treatment

Added 08/03/2011:

13. Patients with non healing wound, ulcer or bone fracture

14. History or evidence of thrombotic or haemorrhagic disorders

15. Patients taking warfarin

16. Uncontrolled hypertension

17. Previous CVA, TIA or SAH within 6 months prior to randomisation

18. Patient prescribed biphosphonates

**Date of first enrolment**

21/01/2010

**Date of final enrolment**

01/12/2014

## **Locations**

**Countries of recruitment**

United Kingdom

England

France

Germany

Italy

Norway

**Study participating centre**

**Royal Marsden Hospital**

London

United Kingdom

SW3 6JJ

## **Sponsor information**

## Organisation

University College London (UK)

## ROR

<https://ror.org/02jx3x895>

## Funder(s)

### Funder type

Charity

### Funder Name

Cancer Research UK will provide funding for the UK trial sites. The sources of funding for non-UK sites have not yet been finalised as of 15/07/2008.

## Results and Publications

### 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? |
|--------------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a>      | results | 01/06/2019   | 25/04/2019 | Yes            | No              |
| <a href="#">Basic results</a>        |         |              |            | No             | No              |
| <a href="#">HRA research summary</a> |         |              | 28/06/2023 | No             | No              |