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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

Submission date 15/07/2008	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 30/07/2008	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 25/04/2019	**Condition category** Cancer	[_] 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

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Additional identifiers

EudraCT/CTIS number
2008-000837-23

IRAS number

ClinicalTrials.gov number
NCT01081262

Secondary identifying numbers
UCL/07/095

Study information

Scientific Title
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 (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

Study design
Phase III multicentre randomised controlled trial

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
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^2, IV, given on day 1

Research arm: 6 cycles of chemotherapy with the following:
1. Oxaliplatin 130 mg/m^2, IV, given on day 1
2. Capecitabine 850 mg/m^2 given twice per day, oral tablets, on the first 14 days of every 21 day cycle (total daily dose 1,700 mg/m^2)

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

Secondary outcome measures
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

Overall study start date
21/01/2010

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

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
330

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 arryhthmia 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
England

France

Germany

Italy

Norway

United Kingdom

Study participating centre
Royal Marsden Hospital
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Sponsor information

Organisation
University College London (UK)

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Sponsor type
University/education

Website
http://www.ucl.ac.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

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?
Basic results				No	No
Results article	results	01/06/2019	25/04/2019	Yes	No
HRA research summary			28/06/2023	No	No