ISRCTN52615671 https://doi.org/10.1186/ISRCTN52615671

Paclitaxel plus carboplatin (TC) therapy versus irinotecan plus cisplatin (CPT-P) therapy as a first-line chemotherapy in clear cell ovarian cancer

Submission date 12/05/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 12/05/2010	**Overall study status** Completed	
Last Edited 25/10/2022	**Condition category** Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/A-trial-comparing-two-combinations-chemotherapy-clear-cell-ovarian-cancer

Contact information

Type(s)
Scientific

Contact name
Ms Karen Carty

Contact details
1053 Great Western Road
Glasgow
United Kingdom
G12 0YN

Additional identifiers

Clinical Trials Information System (CTIS)
2007-007849-13

Protocol serial number
5275

Study information

Scientific Title
Randomised phase III trial of paclitaxel plus carboplatin (TC) therapy versus irinotecan plus cisplatin (CPT-P) therapy as a first-line chemotherapy for clear cell carcinoma of the ovary

Acronym
CCC-1 (JGOG 3017/GCIG)

Study objectives
To compare the efficacy and safety of standard arm of paclitaxel plus carboplatin and experimental arm of irinotecan plus cisplatin in clear cell carcinoma of the ovary.

Primary objective: progression-free survival
Secondary objectives: overall survival, response assessment, adverse events (frequency and grade)

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West 5 Research Ethics Committee, 11/11/2008, ref: 08/H1010/100

Study design
Multicentre randomised interventional treatment trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: National Cancer Research Network; Subtopic: Gynaecological Cancer; Disease: Ovary

Interventions
Experimental arm:
Irinotecan 60 mg/m^2 intravenous (IV) on days 1, 8 and 15
Cisplatin 60 mg/m^2 IV on day 1
This combination is given every 4 weeks (28 days) for 6 cycles. Patients will be followed up for 2.25 years after completing or discontinuing the study treatment.

Standard arm:
Paclitaxel: 175 mg/m^2 IV on day 1
Carboplatin: AUC 6 IV on day 1
This combination given every 3 weeks (21 days) for 6 cycles. Patients will be followed up for 2.25 years after completing or discontinuing the study treatment.

Follow-up length: 27 months
Study entry: registration and one or more randomisations

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Paclitaxel, carboplatin, irinotecan, cisplatin

Primary outcome(s)
Progression-free survival: patients are followed up clinically every 2 months until disease progression

Key secondary outcome(s))
1. Adverse events: adverse event data will be collected during the treatment phase of the study
2. Overall survival: patients will be followed up at least until 36 months post-treatment
3. Response rate: to confirm best response to treatment, patients are scanned (computed tomography [CT]/magnetic resonance imaging [MRI]) pre-treatment

Completion date
31/12/2010

Eligibility

Key inclusion criteria
1. Patients with a histological diagnosis of clear cell carcinoma of the ovary, International Federation of Gynecology and Obstetrics (FIGO) stage I to IV. All patients must have have had a appropriate surgery for ovarian carcinoma with appropriate tissue available for histological evaluation. For patients participating in the trial from the UK, Central Pathology Review will take place prior to entry to confirm patients' eligibility.
2. Eastern Cooperative Oncology Group (ECOG) performance status 0 - 1
3. Reasonable organ function: must be assessed within 14 days of registration
4. Patients must have signed informed consent
5. Patients must be enrolled within 6 weeks of comprehensive surgery
6. Females aged over 18 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Total final enrolment

667

Key exclusion criteria
1. Patients with a current diagnosis of epithelial ovarian cancer of low malignant potential (borderline carcinomas)
2. Patients with a synchronous primary endometrial cancer, or a past history of primary endometrial cancer
3. Prior chemotherapy or radiation to treat the current disease
4. Patients who received intraperitoneal chemotherapy at time of operation
5. Prior diagnosis of malignancy (other than non-melanoma skin cancer or other malignancies curatively treated and greater than 5 years without evidence of recurrence)
6. Patients with diarrhoea greater than Common Terminology Criteria for Adverse Events (CTCAE) grade 1
7. Patients who have received prior radiotherapy
8. Patients who have received prior chemotherapy
9. Patients with an active infection which requires antibiotics

Date of first enrolment
10/05/2010

Date of final enrolment
31/12/2010

Locations

Countries of recruitment
United Kingdom

Scotland

France

Japan

Korea, South

Study participating centre
Gartnavel General Hospital
1053 Great Western Road
Glasgow
United Kingdom
G12 0YN

Sponsor information

Organisation

Greater Glasgow Health Board (North Glasgow University Hospitals Division) (UK)

ROR
https://ror.org/05kdz4d87

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (CRUK) (UK) (ref: C10382/A8964)

Alternative Name(s)
CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

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

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	20/08/2016		Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Plain English results			25/10/2022	No	Yes