

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/05/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 25/10/2022	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-two-combinations-chemotherapy-clear-cell-ovarian-cancer>

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

2007-007849-13

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Topic: National Cancer Research Network; Subtopic: Gynaecological Cancer; Disease: Ovary

Interventions

Experimental arm:

Irinotecan 60 mg/m² intravenous (IV) on days 1, 8 and 15

Cisplatin 60 mg/m² 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/m² 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 measure

Progression-free survival: patients are followed up clinically every 2 months until disease progression

Secondary outcome measures

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

Overall study start date

10/05/2010

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 had 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

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

Planned sample size: 652; UK sample size: 120

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**

France

Japan

Korea, South

Scotland

United Kingdom

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)

Sponsor details

300 Balgray Hill Road
Glasgow
Scotland
United Kingdom
G21 3UR

Sponsor type

Hospital/treatment centre

Website

<http://www.ngt.org>

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, CRUK

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

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?
Results article	results	20/08/2016		Yes	No
Plain English results			25/10/2022	No	Yes
HRA research summary			28/06/2023	No	No