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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

Registration date
12/05/2010

Last Edited
25/10/2022

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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Additional identifiers

EudraCT/CTIS number
2007-007849-13

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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/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 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 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

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