

An international, five-arm randomised trial of carboplatin and paclitaxel versus triplet or sequential doublet combination in patients with epithelial ovarian cancer or primary peritoneal carcinoma

Submission date 18/05/2001	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 18/05/2001	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 22/10/2018	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Study website

<http://www.ctu.mrc.ac.uk/studies/ICON5.asp>

Contact information

Type(s)

Scientific

Contact name

Dr P Harper

Contact details

Medical Oncology
3rd Floor Thomas Guy House
Guy's Hospital
St Thomas Street
London
United Kingdom
SE1 9RT

-

abc@123.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00011986

Secondary identifying numbers

E164/58

Study information

Scientific Title

An international, five-arm randomised trial of carboplatin and paclitaxel versus triplet or sequential doublet combination in patients with epithelial ovarian cancer or primary peritoneal carcinoma

Acronym

ICON5/GOG182

Study objectives

To evaluate a variety of chemotherapy regimes for patients with advanced stage (FIGO III-IV) epithelial ovarian or serious primary peritoneal carcinoma. Efficacy will be determined through analysis of overall survival and progression free survival.

The trial will also compare the toxicities and adverse effects of each treatment regimen, describe the dose density and collative dose delivery for each regime, compare response rates in patients with measurable disease. In the UK, evaluate the impact of regimes on quality of life, evaluate the impact of regimes on resource use and quality-adjusted life-years, collect and store genetic material for future studies of molecular genetics.

The trial includes two stages, at the end of the first stage only those treatment arms that appear promising on the basis of progression free survival will continue in to the second stage which aims to evaluate the impact of the regimes on overall survival.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet**Health condition(s) or problem(s) studied**

Ovarian cancer and peritoneal carcinoma

Interventions

Arm I: Taxol 175 mg/m² day one, Carboplatin AUC6 or AUC(EDTA)5 iv day one, eight cycles

Arm II: Taxol 175 mg/m², day one, Gemzar 800 mg/m² days one and eight, Carboplatin AUC5 or AUC(EDTA)4, day one, eight cycles

Arm III: Taxol 175 mg/m² day one, Caelyx 30 mg/m² day one every other cycle, Carboplatin AUC5 or AUC(EDTA)4 day one, eight cycles

Arm IV: Hycamtin 1.25 mg/m² days one, two and three, Carboplatin AUC5 or AUC(EDTA)4 day three, four cycles, then four cycles of Arm I

Arm V: Gemzar 1000 mg/m², days one and eight, Carboplatin AUC6 or AUC(EDTA)5 day eight, four cycles then four cycles of Arm I

In every case cycles are 21 days long. Chemotherapy continues unless disease progression or unacceptable toxicity occurs. Dose reductions or delays for toxicity are defined in the full protocol.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Carboplatin and paclitaxel

Primary outcome measure

Overall survival.

Secondary outcome measures

1. Progression free survival
2. Response rate (in patients with measurable disease)
3. Toxicity and symptoms
4. Dose and dose intensity
5. Patients assessment of quality of life and acceptability of treatment, health economics
6. Molecular genetics (future study)

Overall study start date

01/03/2002

Completion date

31/12/2007

Eligibility

Key inclusion criteria

1. Stage III or IV ovarian or serious primary peritoneal carcinoma, following appropriate surgery
2. Tumor tissue available for histological evaluation
3. Adequate bone marrow liver kidney and neurological function
4. World Health Organisation (WHO) performance status zero to two
5. Fit and able to take part in trial treatments and follow-up
6. Informed consent

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

4000

Key exclusion criteria

1. Concomitant or previous malignancies likely to interfere with protocol treatments
2. Patient has received radiotherapy or chemotherapy to any abdominal or pelvic tumour
3. Acute hepatitis, infection or Gastrointestinal bleeding
4. Women of childbearing age who will not use adequate contraception or are breastfeeding

Date of first enrolment

01/03/2002

Date of final enrolment

31/12/2007

Locations

Countries of recruitment

England

United Kingdom

United States of America

Study participating centre

Medical Oncology

London

United Kingdom

SE1 9RT

Sponsor information

Organisation

Medical Research Council (MRC) (UK)

Sponsor details

20 Park Crescent

London

United Kingdom

W1B 1AL

+44 (0)20 7636 5422

clinical.trial@headoffice.mrc.ac.uk

Sponsor type

Research council

Website

<http://www.mrc.ac.uk>

Funder(s)

Funder type

Research council

Funder Name

Medical Research Council (MRC) (UK)

Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

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

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Plain English results				No	Yes
Results article	results:	01/08/2003		Yes	No
Results article	results:	20/03/2009		Yes	No