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A randomised study comparing carboplatin and carboplatin with thalidomide in patients with Stage Ic-IV Ovarian Cancer

Submission date 19/08/2002	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 19/08/2002	**Overall study status** Completed	
Last Edited 07/12/2012	**Condition category** Cancer	

Plain English summary of protocol
http://www.cancerresearchuk.org/cancer-help/trials/carboplatin-and-thalidomide-in-women-with-ovarian-cancer

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00004876

Secondary identifying numbers
96.084

Study information

Scientific Title

Study objectives
Drugs used in chemotherapy use different ways to stop tumour cells from dividing so they stop growing or die. Thalidomide may stop the growth of ovarian cancer by stopping blood flow to the tumour.

This randomised phase II trial is studying how well giving carboplatin together with thalidomide works compared to carboplatin alone in treating patients with ovarian epithelial cancer.

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

Interventions
Patients entering the trial will be randomised to receive carboplatin (every 4 weeks for a maximum of six cycles) only or carboplatin with thalidomide (for 24 weeks commencing on the first day of carboplatin therapy and ceasing 4 weeks after the last cycle of chemotherapy).

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Carboplatin, thalidomide

Primary outcome measure
1. Safety
2. Response
3. Markers of angiogenesis

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/08/1999

Completion date
31/12/2005

Eligibility

Key inclusion criteria
1. Histologically confirmed epithelial ovarian cancer
2. Post-menopausal or if pre-menopausal, patients must have had a bilateral salpingo-oophorectomy and/or a total abdominal hysterectomy
3. Stage Ic-IV ovarian cancer
4. Aged over 18 years
5. World Health Organisation (WHO) performance status 0, 1 or 2
6. Written informed consent
7. No previous carboplatin/cisplatin treatment for ovarian cancer
8. No other current invasive malignancy
9. Neither pregnant or with the ability to become pregnant
10. No chronic neurological disease causing peripheral neuropathy
11. No diabetes mellitus

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
30

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/08/1999

Date of final enrolment
31/12/2005

Locations

Countries of recruitment
United Kingdom

Study participating centre
Oxford Radcliffe Hospital
Oxford
United Kingdom
0X3 9DU

Sponsor information

Organisation
Cancer Research UK (CRUK) (UK)

Sponsor details
PO Box 123
Lincoln's Inn Fields
London
United Kingdom
WC2A 3PX
+44 (0)207 317 5186
kate.law@cancer.org.uk

Sponsor type
Charity

Website
http://www.cancer.org.uk

ROR
https://ror.org/054225q67

Funder(s)

Funder type

Charity

Funder Name
Cancer Research UK (CRUK) (UK)

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

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	01/08/2011		Yes	No