

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

<b>Submission date</b> 19/08/2002	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 19/08/2002	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 07/12/2012	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## 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

### Contact name

Dr TS Ganesan

### Contact details

Oxford Radcliffe Hospital  
Oxford  
United Kingdom  
OX3 9DU

## Additional identifiers

### ClinicalTrials.gov (NCT)

NCT00004876

### Protocol serial number

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

**Study type(s)**

Treatment

**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(s)**

1. Safety
2. Response
3. Markers of angiogenesis

**Key secondary outcome(s))**

No secondary outcome measures

**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

### Healthy volunteers allowed

No

### Age group

Adult

### Lower age limit

18 years

### Sex

Female

### 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  
OX3 9DU

## Sponsor information

### Organisation

Cancer Research UK (CRUK) (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, 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

IPD sharing plan summary

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
-------------	---------	--------------	------------	----------------	-----------------

[Results article](#)

results

01/08/2011

Yes

No