

A comparison of treosulfan and carboplatin in patients with ovarian cancer not suitable for treatment with cisplatin

Submission date 01/07/2001	Recruitment status Stopped	☐ Prospectively registered ☐ Protocol
Registration date 01/07/2001	Overall study status Stopped	☐ Statistical analysis plan ☒ Results
Last Edited 04/01/2012	Condition category Cancer	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr - -

Contact details

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NW1 2DA

Additional identifiers

Protocol serial number

G44

Study information

Scientific Title

Study objectives

Not provided at time of registration

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Ovarian cancer

Interventions

1. Carboplatin: 6 x (glomerular filtration rate (GFR)+ 25) mg intravenous every 28 days for six cycles
2. Treosulfan: 7 g/m² intravenous every 28 days for six cycles

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

treosulfan and carboplatin

Primary outcome(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

Completion date

15/07/1998

Reason abandoned (if study stopped)

Objectives no longer viable

Eligibility**Key inclusion criteria**

1. Not considered for cisplatin ≥ 75 mg/m²
2. Stages Ic-IV
3. Histologically proven epithelial ovarian cancer
4. Life expectancy ≥ 3 months
5. World Health Organisation (WHO) Performance status 0-3
6. Creatinine clearance ≥ 20 ml/min White Blood Cell (WBC) Count $\geq 3.5 \times 10^9$ /l Platelets $\geq 100 \times 10^9$ /l

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex**Key exclusion criteria**

Not provided at time of registration

Date of first enrolment

01/01/1993

Date of final enrolment

15/07/1998

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

UKCCCR Register Co-ordinator

London

United Kingdom

NW1 2DA

Sponsor information**Organisation**

Cancer Research UK (CRUK) (UK)

ROR

<https://ror.org/054225q67>

Funder(s)

Funder type

Charity

Funder Name

Cancer Research 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	01/01/2006		Yes	No