

To compare intravenous treosulphan with intravenous treosulphan plus cisplatin in advanced ovarian cancer

Submission date 19/08/2002	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 19/08/2002	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 24/10/2019	Condition category Cancer	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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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Additional identifiers

Protocol serial number

O10

Study information

Scientific Title

To compare intravenous treosulphan with intravenous treosulphan plus cisplatin in advanced ovarian cancer

Study objectives

Not provided at time of registration

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)

Not Specified

Health condition(s) or problem(s) studied

Ovarian cancer

Interventions

Patients are randomised to one of two treatment arms:

1. Arm A: Treosulphan given every 3 weeks
2. Arm B: Treosulphan plus cisplatin repeated every 3 weeks

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Treosulphan

Primary outcome(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

Completion date

01/08/1995

Eligibility**Key inclusion criteria**

1. International Federation of Gynecology and Obstetrics (FIGO) stage Ic or II (except well differentiated), III or IV ovarian cancer
2. Histological confirmation of carcinoma of epithelial origin

3. Aged 75 or under
4. Life expectancy >2 months
5. No extensive prior chemotherapy (no prior treosulfan or cisplatin at all, and not more than one course of other cytotoxic treatment)
6. No radical prior radiotherapy to pelvis and/or abdomen within preceding 3 months
7. No depressed marrow function or gastro-intestinal bleeding
8. Good renal function

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Not Specified

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/01/1993

Date of final enrolment

01/08/1995

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

UKCCCR Register Co-ordinator

London

United Kingdom

NW1 2DA

Sponsor information**Organisation**

Leo Pharmaceuticals

ROR

<https://ror.org/05tzrdd39>

Funder(s)

Funder type

Industry

Funder Name

Leo Pharmaceuticals (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration