

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

UKCCCR Register Co-ordinator
MRC Clinical Trials Unit
222 Euston Road
London
United Kingdom
NW1 2DA

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

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 measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/01/1993

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

Age group

Adult

Sex

Not Specified

Target number of participants

Not provided at time of registration

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

England

United Kingdom

Study participating centre
UKCCCR Register Co-ordinator
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
Leo Pharmaceuticals

Sponsor details
Longwick Road
Princes Risborough
United Kingdom
HP27 9RR
+44 1844 347333
medical-info.uk@leo-pharma.com

Sponsor type
Industry

Website
<http://www.leo-pharma.co.uk/w-site/leo-gb/docs-gb.nsf>

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

Funder(s)

Funder type
Industry

Funder Name
Leo Pharmaceuticals (UK)

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