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

Submission date	Recruitment status	[ ] Prospectively registered
19/08/2002	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
19/08/2002	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
24/10/2019	Cancer	[ ] 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

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