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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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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

Primary study design
Interventional

Study design
Randomised controlled trial

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