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International Study for the Salvage Treatment of Germ Cell Tumours

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 11/07/2014	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr - -

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
GE301

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

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
Testis

Interventions
1. Group A: Chemotherapy with etoposide, ifosfamide, mensa and CDDP (PEI) or etoposide, ifosfamide, mensa and CDDP (VEIP). Treatment cycle repeated every 21 days for four cycles.
2. Group B: Chemotherapy with PEI or VEIP. Treatment cycle repeated every 21 days for three cycles followed by myeloablative chemotherapy with carboplatin, etoposide, cyclophosphamide and mensa (CarboPec) plus ABMT/PBSC.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Cancer drugs

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
15/01/1994

Completion date
31/12/2004

Eligibility

Key inclusion criteria
1. Males aged >16 years
2. Germ cell tumours, either testicular or extragonadal
3. Platinum combination chemotherapy as first line chemotherapy
4. Remission after complete response from first line chemotherapy
5. Partial responder patients after first line chemotherapy, including patients with resection of viable malignancy after first line chemotherapy with elevated tumour markers
6. World Health Organisation (WHO) performance status grade 0-2
7. Seminoma patients relapsing after complete response after cisplatin-based chemotherapy or partial response under cisplatin-based chemotherapy
8. Refactory patients are to be excluded
9. Patients with pure seminoma treated with carboplatin are excluded
10. No other malignancy
11. No medical contraindications to protocol treatments

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
15/01/1994

Date of final enrolment
31/12/2004

Locations

Countries of recruitment

England

France

United Kingdom

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

Sponsor information

Organisation
Institut Gustave-Roussy (France)

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Sponsor type
Research organisation

Website
http://www.igr.fr

ROR
https://ror.org/0321g0743

Funder(s)

Funder type
Research organisation

Funder Name
Institut Gustave-Roussy (France)

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