

# International Study for the Salvage Treatment of Germ Cell Tumours

<b>Submission date</b> 19/08/2002	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 19/08/2002	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 11/07/2014	<b>Condition category</b> 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**  
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**Contact details**  
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## Additional identifiers

**Protocol serial number**  
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

**Primary study design**

Interventional

**Study design**

Randomised controlled trial

**Study type(s)**

Not Specified

**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(s)**

Not provided at time of registration

**Key secondary outcome(s)**

Not provided at time of registration

**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. Refractory 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

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

Male

### **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**

United Kingdom

England

France

### **Study participating centre**

UKCCCR Register Co-ordinator

London

United Kingdom

NW1 2DA

## **Sponsor information**

**Organisation**

Institut Gustave-Roussy (France)

**ROR**

<https://ror.org/0321g0743>

**Funder(s)****Funder type**

Research organisation

**Funder Name**

Institut Gustave-Roussy (France)

**Results and Publications****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration