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Phase I/II multicentre trial of salvage chemotherapy with Gem-TIP for relapsed germ cell cancer

Submission date 31/03/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 31/03/2010	**Overall study status** Completed	
Last Edited 04/04/2022	**Condition category** Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-chemotherapy-combination-Gem-TIP-advanced-germ-cell-cancer

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2004-004804-19

ClinicalTrials.gov (NCT)
NCT00551122

Protocol serial number
1447

Study information

Scientific Title
A non-randomised multicentre phase I/II interventional trial of a tolerable salvage chemotherapy regimen for patients with metastatic germ cell cancer who have failed first-line chemotherapy

Acronym
Gem-TIP

Study objectives
The purpose of this study is to develop a tolerable, highly active, salvage chemotherapy regimen to be used in patients with metastatic germ cell cancer who have failed first-line chemotherapy.

On 01/03/2011 the target number of participants was changed from 28 to 14.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Southampton and South west Hampshire REC A, 05/04/2005, ref: 05/Q1702/22

Study design
Non-randomised multicentre interventional treatment trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: National Cancer Research Network; Subtopic: Testis Cancer; Disease: Testis

Interventions
4 cycles of chemotherapy, 4 cycles of chemotherapy using gemcitabine and paclitaxel, ifosfamide, cisplatin (TIP) regimen.

Follow Up Length: 12 month(s)
Study Entry : Registration only

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Gemcitabine, paclitaxel, ifosfamide, cisplatin

Primary outcome(s)
To assess the maximally tolerated dose of Gem-TIP (+Granulocyte colony-stimulating factor [+GCSF]) when compared with TIP, established in the phase 1 aspect of the trial

Key secondary outcome(s))
To measure response rates and failure free survival after Gem-TIP alone, assessed at 1, 2, 3, 4, 6, 8 10 and 12 months post-treatment

Completion date
04/09/2011

Eligibility

Key inclusion criteria
1. First relapse after single previous cisplatin-containing combination chemotherapy for metastatic extracranial primary germ cell cancer, seminoma and non-seminoma, male or female patients
2. All cases must have either rising serum markers (alphafetoprotein [AFP], human chorionic gonadotropin [HCG]) on sequential measurement, or biopsy-proven unresectable germ cell cancer. Patients with completely resected cancer are not eligible for this study. Patients with late relapse (greater than 2 years post-initial chemotherapy) should be considered for surgery rather than chemotherapy where technically feasible. Patients with cerebral metastases alone are not eligible. Patients with progressive cerebral and systemic disease may be considered for this study. However, it is recommended that cranial irradiation also be considered a component of care.
3. Aged 16 - 60 years
4. Considered medically and psychologically fit to receive this intensive chemotherapy schedule
5. White blood cells (WBC) greater than 3.5 x 10^9/l. Platelets greater than 130 x 10^9/l
6. Glomerular filtration rate (24 hours)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
20

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
11/10/2005

Date of final enrolment
04/09/2011

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Southampton Clinical Trials Unit, MP 131
Southampton
United Kingdom
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Sponsor information

Organisation
Southampton University Hospitals NHS Trust (UK)

ROR
https://ror.org/0485axj58

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (CRUK) (UK) - Clinical Trials Advisory and Awards Committee (CTAAC) grant

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2018	08/03/2019	Yes	No
Abstract results	conference abstract	01/06/2014	08/03/2019	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Plain English results				No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes