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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

Study website
http://www.ctu.soton.ac.uk

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
2004-004804-19

IRAS number

ClinicalTrials.gov number
NCT00551122

Secondary identifying numbers
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

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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

Secondary outcome measures
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

Overall study start date
11/10/2005

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

Age group
Adult

Sex
Both

Target number of participants
14 (28 at time of registration)

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
England

United Kingdom

Study participating centre
University of Southampton Clinical Trials Unit, MP 131
Southampton
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SO16 6YD

Sponsor information

Organisation
Southampton University Hospitals NHS Trust (UK)

Sponsor details
Tremona Road
Southampton
England
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Sponsor type
Hospital/treatment centre

Website
http://www.suht.nhs.uk/home.aspx

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Plain English results				No	Yes
Abstract results	conference abstract	01/06/2014	08/03/2019	No	No
Results article	results	01/12/2018	08/03/2019	Yes	No