

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 31/03/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 04/04/2022	Condition category Cancer	<input type="checkbox"/> Individual participant data

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

Mrs Kelly Cozens

Contact details

University of Southampton Clinical Trials Unit, MP 131
Southampton General Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD

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 $3.5 \times 10^9/l$. Platelets greater than $130 \times 10^9/l$
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

United Kingdom

SO16 6YD

Sponsor information

Organisation

Southampton University Hospitals NHS Trust (UK)

Sponsor details

Tremona Road

Southampton

England

United Kingdom

SO16 6YD

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