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Radiotherapy with weekly gemcitabine (GEM)

Submission date 30/07/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/07/2010	**Overall study status** Completed	
Last Edited 19/10/2018	**Condition category** Cancer	

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/a-trial-looking-at-radiotherapy-and-gemcitabine-for-people-with-bladder-cancer

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1368

Study information

Scientific Title

Phase II study of radiotherapy with concurrent weekly gemcitabine in muscle-invasive bladder cancer

Study objectives
The aim of this prospective phase II trial was to determine the response of muscle invasive bladder cancer (MIBC) to concurrent chemoradiotherapy using weekly gemcitabine with four weeks' radiotherapy (RT) (GemX).

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Manchester Local Research and Ethics Committee approved (ref: 03/SM/097)

Study design
Multicentre non-randomised 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

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

Interventions
Each cycle of concurrent chemotherapy comprised 100 mg/m^2 gemcitabine given as an intravenous infusion over 30 minutes 2 - 4 hours before radiotherapy (RT) on day 1. Conformal radiotherapy using four fields and multi-leaf collimators was delivered to the whole bladder with a minimum 2 cm margin at the involved wall. A total dose of 52.5 Gy was given as 20 fractions within 28 days. Gemcitabine was administered once weekly during RT on days 1, 8, 15 and 22.

Study entry: Registration only

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)

Gemcitabine

Primary outcome measure
Tumour response, measured three months after completion of treatment

Secondary outcome measures
1. Toxicity
2. Survival

Overall study start date
01/07/2003

Completion date
07/08/2007

Eligibility

Key inclusion criteria
1. Histologically confirmed T2-3 N0M0 transitional cell carcinoma (TCC) of the bladder*
2. Life expectancy greater than 3 months
3. World Health Organization (WHO) performance status 0 2
4. Patients opting for bladder preservation who are able and motivated to comply with follow up
5. Maximal achievable transurethral resection of bladder tumour (TURBT)
6. Serum creatinine less than 1.5 x upper limit of normal (ULN)
7. Haemoglobin (Hb) greater than 10 g/dl, platelets greater than 100,000/mm^3, white cell count (WCC) greater than 2000/mm^3
8. Aged greater than 18 years
9. Provided informed consent

*Patients with TCC in whom biopsy fails to demonstrate histological evidence of muscle invasion but where magnetic resonance (MR) demonstrates unequivocal evidence of deep muscle invasion can be accepted for trial entry

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
Planned sample size: 50

Key exclusion criteria

1. Residual tumour with any unidimensional measurement greater than or equal to 7 cm following TURBT
2. Poor bladder function:
2.1. Any WHO bladder symptom score equalling 3 or greater than or equal to two bladder symptom scores equalling 2
2.2. Documented bladder capacity less than or equal to 200 ml
3. Abnormal liver function tests (LFT) (bilirubin greater than 1.3 x ULN, alkaline phosphatase greater than 5 x ULN, transaminases greater than 5 x ULN)
4. Previous radiotherapy to pelvis
5. More than one instillation of intravesical cytotoxic chemotherapy or immunotherapy
6. Any previous systemic chemotherapy
7. Radiotherapy planning target volume (PTV) greater than 1000cm^3
8. Any prior malignancy (excluding basal cell carcinoma [BCC])
9. Pre-existing medical conditions that preclude this treatment
10. Pregnant or breast-feeding
11. Not able to use appropriate and/or adequate contraception during and for 3 months after the study

Date of first enrolment
01/07/2003

Date of final enrolment
07/08/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
550 Wilmslow Road
Manchester
United Kingdom
M20 4BX

Sponsor information

Organisation
Christie Hospital NHS Foundation Trust (UK)

Sponsor details
550 Wilmslow Road
Manchester

England
United Kingdom
M20 4BX

Sponsor type
Hospital/treatment centre

Website
http://www.christie.nhs.uk/

ROR
https://ror.org/03v9efr22

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Christie Hospital NHS Foundation Trust (UK)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Plain English results				No	Yes
Results article	results	20/02/2011		Yes	No