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A phase II trial of gemcitabine plus carboplatin in advanced transitional cell carcinoma of the urothelium

Submission date 25/02/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 14/03/2007	**Overall study status** Completed	
Last Edited 04/01/2008	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ZJWST491010G20518

Study information

Scientific Title

Study objectives
Recent studies have demonstrated the effectiveness of cisplatin-based combinations in patients with advanced Transitional Cell Carcinoma (TCC) of the urothelium. Concern over cisplatin toxicity instigated a search for alternative regimens. The aim of the study was to evaluate the activity and tolerability of gemcitabine plus carboplatin combination as first-line treatment in patients with advanced transitional cell carcinoma of the urothelium.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The First Affiliated Hospital Ethical Review Board, School of Medicine, Zhejiang University. Approved on 10/12/2002. Ethics Review No. 26 (2002)

Study design
An open label, multi-centre, phase II study

Primary study design
Interventional

Secondary study design
Multi-centre

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Advanced transitional cell carcinoma of the urothelium

Interventions
Patients with advanced TCC were treated with gemcitabine 1200 mg/m2 on days 1 and 8 and carboplatin area under the concentration-time curve (AUC) 5 on day 1 every 21 days.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)

Gemcitabine, carboplatin

Primary outcome measure
1. Objective response rate
2. Tolerability

Secondary outcome measures
1. Overall survival
2. Progression-free survival

Overall study start date
01/01/2003

Completion date
15/06/2006

Eligibility

Key inclusion criteria
1. Patients with locally advanced or metastatic transitional cell carcinoma of the bladder, ureter or renal pelvis were eligible for this study
2. Patients were required to have histologically or cytologically proven locally advanced or metastatic transitional cell carcinoma of the bladder, ureter or renal pelvis
3. Prior cytotoxic treatment either in the adjuvant setting or for metastatic disease was permitted if the treatment had been completed at least six months prior to enrollment in the study
4. Prior radiotherapy was permitted but must have been completed at least six weeks prior to enrollment
5. Eastern Cooperative Oncology Group (ECOG) performance status less than or equal to 2
6. A life expectancy at least 3 months
7. Age between 18 and 75 years
8. Adequate bone marrow: absolute neutrophil count more than or equal to 1.5 x 10^9/L, platelet count more than or equal to 100 x 10^9/L, and hemoglobin more than or equal to 100 g /L
9. Adequate hepatic functions: aspartate aminotransferase/alanine aminotransferase, AST/ALT less than or equal to 3.0 times the Upper Normal Limit (UNL) and serum bilirubin less than or equal to 1.5 x UNL
10. Adequate renal functions: serum creatinine less than or equal to 1.5 x UNL and creatinine clearance more than or equal to 30 ml/min based on the Calvert formula
11. Adequate normal cardiac function

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
39

Key exclusion criteria
1. Second primary tumor other than non-melanoma skin cancer or in situ cervical carcinoma
2. Central nervous system (CNS) involvement
3. Prior radiotherapy in parameter lesions
4. Concurrent uncontrolled medical illness

Date of first enrolment
01/01/2003

Date of final enrolment
15/06/2006

Locations

Countries of recruitment
China

Study participating centre
79 Qingchun Road
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310003

Sponsor information

Organisation
School of Medicine, Zhejiang University (China)

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Sponsor type
University/education

Website
http://www.cmm.zju.edu.cn/english/

ROR
https://ror.org/00a2xv884

Funder(s)

Funder type
Government

Funder Name
Health Bureau of Zhejiang Province (China)

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?
Results article	Results	09/06/2007		Yes	No