

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
Registration date 14/03/2007	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 04/01/2008	Condition category Cancer	☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

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)

Primary study design

Interventional

Study design

An open label, multi-centre, phase II study

Study type(s)

Treatment

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(s)

1. Objective response rate
2. Tolerability

Key secondary outcome(s)

1. Overall survival
2. Progression-free survival

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 $1.5 \times 10^9/L$, platelet count more than or equal to $100 \times 10^9/L$, 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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Not Specified

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

Hangzhou

China

310003

Sponsor information

Organisation

School of Medicine, Zhejiang University (China)

ROR

<https://ror.org/00a2xv884>

Funder(s)

Funder type

Government

Funder Name

Health Bureau of Zhejiang Province (China)

Results and Publications

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				

[Results article](#)

09/06/2007

Yes

No