

Treatment of Chinese patients with metastatic gastric cancer where resection is not possible

Submission date 19/03/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 15/04/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 09/10/2015	Condition category Cancer	<input type="checkbox"/> 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
N/A

Study information

Scientific Title
Treatment of Chinese patients with metastatic gastric cancer where resection is not possible, with a biweekly combination of S-1 and Paclitaxel (SPA) or a combination of S-1 and Oxaliplatin (SOX)

Acronym
SPA/SOX

Study objectives

The use of S-1 plus Paclitaxel or S-1 plus Oxaliplatin as first-line or second-line treatment will be beneficial in patients with metastatic gastric cancer where resection is not possible

Ethics approval required

Old ethics approval format

Ethics approval(s)

The First Affiliated Hospital Ethical Review Board, School of Medicine, Zhejiang University, 02/05/2010, Ethics Review No. 21 (2010)

Study design

Open-label multi-centre phase II study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Metastatic gastric cancer or where resection is not possible

Interventions

1. Patients were randomized (1:1) according to the following sequences:
 - 1.1. Arm A: S-1 was administered orally (80 mg/m²/day) after meal for 7 days followed by a 7-day rest every 2 weeks with Paclitaxel 120 mg/m²
 - 1.2. Arm B: S-1 was administered orally (80 mg/m²/day) after meal for 7 days followed by a 7-day rest every 2 weeks with oxaliplatin 85 mg/m² as a 2-hour infusion on day 1
2. Toxicity evaluations were based on the National Cancer Institute Common Toxicity Criteria for Adverse Events v3.0
3. Radiological evaluations were conducted at base line and after every three courses
4. At progression, Paclitaxel was replaced by oxaliplatin (Arm A), or oxaliplatin by Paclitaxel (Arm B)

Intervention Type

Drug

Phase

Phase II

Drug/device/biological/vaccine name(s)

1. S-1
2. Paclitaxel
3. Oxaliplatin

Primary outcome(s)

Progression-free survival

Key secondary outcome(s)

1. Overall survival
2. Response rate
3. Safety

Completion date

31/05/2012

Eligibility

Key inclusion criteria

1. Patients with unresectable or metastatic gastric cancer were eligible for this study
2. Patients were required to have histological or cytological proof of locally advanced or metastatic transitional cell carcinoma of the bladder, ureter or renal pelvis
3. Prior cytotoxic treatment in the adjuvant setting 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 4 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 90g/L
9. Adequate hepatic functions: aspartate aminotransferase (AST) and (alanine aminotransferase) ALT less than or equal to 3.0 times the upper normal limit (UNL) and serum bilirubin less than or equal to 1.5
10. Adequate renal functions: serum creatinine less than or equal to 133umol/L
11. Adequate normal cardiac function

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

01/03/2010

Date of final enrolment

31/05/2012

Locations

Countries of recruitment

China

Study participating centre

79 Qingchun Road

Hangzhou

China

310003

Sponsor information

Organisation

Zhejiang University (China)

ROR

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

Funder(s)

Funder type

Government

Funder Name

National Natural Science Foundation of China (Grant No. 81001212) (China)

Alternative Name(s)

Chinese National Science Foundation, Natural Science Foundation of China, National Science Foundation of China, NNSF of China, NSF of China, National Nature Science Foundation of China, Guójiā Zìrán Kēxué Jījīn Wěiyuánhùi, , NSFC, NNSF, NNSFC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

China

Funder Name

Foundation of Zhejiang Provincial Educational Committee (Grant No. Y201019175) (China)

Funder Name

Zhejiang Provincial Health Bureau Foundation (Grant No. 2010KYB036) (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 article	results	01/07/2015		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes