

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

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

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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Hangzhou  
China  
310003

## 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/m<sup>2</sup>/day) after meal for 7 days followed by a 7-day rest every 2 weeks with Paclitaxel 120 mg/m<sup>2</sup>
  - 1.2. Arm B: S-1 was administered orally (80 mg/m<sup>2</sup>/day) after meal for 7 days followed by a 7-day rest every 2 weeks with oxaliplatin 85 mg/m<sup>2</sup> 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?
<a href="#">Results article</a>	results	01/07/2015		Yes	No