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

Submission date	Recruitment status	[_] Prospectively registered
19/03/2011	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
15/04/2011	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
09/10/2015	Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

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)

Primary study design
Interventional

Study design
Open-label multi-centre phase II study

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 withoxaliplatin 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 1.5x10E9/L platelet count more than or equal to 100x10E9/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 Wěiyuánhuì, , 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