Protocol Registration Receipt
08/29/2012

Postoperative IMRT Combined With Capecitabine for Advanced Gastric Cancer Patients

This study is currently recruiting participants.

Verified by Jing Jin, M.D., Chinese Academy of Medical Sciences, August 2012

Sponsor:	Chinese Academy of Medical Sciences
Collaborators:	
Information provided by (Responsible Party):	Jing Jin, M.D., Chinese Academy of Medical Sciences
ClinicalTrials.gov Identifier:	NCT01674959

Purpose

Radiation therapy plus concurrent chemotherapy has been demonstrated a significant improvement in overall and disease-free survival according to Intergroup Trial 0116 in patients with gastric cancer after surgical complete resection. Advantage of application of IMRT has been shown in planning comparison studies for postoperative gastric patients. So the investigators designed the trial to see safety and efficacy of postoperative concurrent chemoradiotherapy of capecitabine combined with IMRT for stage II/II gastric cancer.

Condition	Intervention	Phase
Gastric Cancer	Radiation: concurrent chemoradiation	Phase 2

Study Type: Interventional
Study Design: Treatment, Single Group Assignment, Open Label, N/A, Safety/Efficacy Study
Official Title: Phase II Study of Postoperative Intensity-modulated Radiotherapy (IMRT) Combined With Capecitabine for Stage II/III Gastric Cancer Patients

Further study details as provided by Jing Jin, M.D., Chinese Academy of Medical Sciences:

Primary Outcome Measure:

- feasibility of concurrent IMRT combined with capecitabine for the treatment of gastric cancer patients [Time Frame: 3 months after concurrent chemoradiation] [Designated as safety issue: Yes]
  feasibility of concurrent IMRT combined with capecitabine is defined as toxicities (CTC-AE 3.0) and rate of patients complete concurrent chemoradiation according to protocol.

Secondary Outcome Measures:

- efficacy of concurrent IMRT combined with capecitabine for the treatment of gastric cancer patients [Time Frame: 3 years after concurrent chemoradiation] [Designated as safety issue: No]
  efficacy of concurrent IMRT combined with capecitabine for the treatment of gastric cancer patients in this trial is defined as 3-year overall survival and 3-year relapse free survival.

Estimated Enrollment: 40
Study Start Date: October 2011
Estimated Study Completion Date: December 2017
Estimated Primary Completion Date: December 2014

Arms	Assigned Interventions
Experimental: concurrent chemoradiation • Radiation: concurrent chemoradiotherapy Postoperative radiotherapy regimen: Therapy plan system was formulated by Computed tomographic (CT) simulation. Radiation was delivered with 6MV photons. Radiotherapy consisted of 4500 cGy of radiation at 180 cGy per day, five days per week for five weeks, to the tumor bed, to the margins of resection or the stoma, to the regional nodes. Protection of spinal cord, heart, liver and kidney should be considered. Postoperative current chemotherapy regimen: capecitabine(1,600 mg/m2 per day for 5 weeks).	Radiation: concurrent chemoradiation postoperative Intensity-modulated radiotherapy (IMRT) combined with capecitabine for high risk gastric cancer patients Radiation: concurrent chemoradiotherapy Postoperative radiotherapy regimen: Therapy plan system was formulated by Computed tomographic (CT) simulation. Radiation was delivered with 6MV photons. Radiotherapy consisted of 4500 cGy of radiation at 180 cGy per day, five days per week for five weeks, to the tumor bed, to the margins of resection or the stoma, to the regional nodes. Protection of spinal cord, heart, liver and kidney should be considered. Postoperative chemotherapy regimen: capecitabine(1,600 mg/m2 per day for 5 weeks).

In Intergroup 0116, only 64% patients in concurrent chemoradiation group completed treatment as planed, but in recently reported ARTIST trial, capecitabine was admitted to concurrent with radiotherapy,patients who completed treatment as planed in concurrent group reach high as 80%. IMRT is an advanced radiotherapy technology which allows high conformal dose distribution to Planing Tumor Volume (PTV) and low dose to organ at risk. The purpose of this study is to evaluate feasibility and efficacy of concurrent IMRT combined with capecitabine for the treatment of gastric cancer patients after D1/2 surgery.

Eligibility

Ages Eligible for Study: 18 Years to 75 Years
Genders Eligible for Study: Both

Inclusion Criteria:

1. Postoperative histologically confirmed advanced adenocarcinoma of the stomach or the gastroesophageal junction.
2. Age of 18 to 75, Karnofsky score higher than 70.
3. Postoperative histologically conformed metastasis in perigastric lymph nodes and/or tumor invasion to muscularis propria or subserosa, without positive incisal margin. Stage II/III(AJCC 7th).
4. No severe functional damage of major organ, normal blood cell, normal liver and kidney function.
5. No clinical findings of distant metastasis.
6. Predictive survival time longer than 6 months.

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Exclusion Criteria:

1. Peritoneal carcinomatosis, as diagnosed by mandatory laparoscopy or distant metastasis
2. Concurrent treatment with other experimental drugs or other anti-cancer therapy, or treatment within a clinical trial within 30 days prior to trial entry
3. Severe or uncontrolled cardiovascular disease (congestive heart failure NYHA III or IV, no myocardial infarction within the last 12 months, unstable angina pectoris, or significant arrhythmia)
4. Active or uncontrolled infection.
5. Definitive contraindications for the use of corticosteroids as premedication
6. Prior systemic (chemo- or targeted) treatment. Prior radiotherapy to the upper abdomen
7. Any contraindication to treatment with cetuximab, capecitabine or cisplatin
8. Previous malignancy within 5 years, with the exception of adequately treated cervical carcinoma in situ or localized non-melanoma skin cancer
9. Known hypersensitivity against any of the study drugs (capecitabine)

Contacts and Locations

Contacts

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Principal Investigator: jing jin, professor

Investigators

Principal Investigator:	jing jin, professor	Cancer Hospital, Chinese Academy of Medical Science

More Information

Responsible Party:	Jing Jin, M.D., Attending doctor of Dept. radiation oncology, Cancer Hospital, Chinese Academy of Medical Sciences
Study ID Numbers:	2011 CH-GI-024
Health Authority:	China: State Food and Drug Administration