Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Oct 2026

Clinical trial to evaluate the resectability rate and tumor response to neoadjuvant chemo radiotherapy in patients with locally advanced proximal gastric cancer and esophagogastric cancer.

Protocol summary

Summary

The aim of the study: Evaluation of resectability rate and tumor response to neoadjuvant chemo radiotherapy in patients with locally advanced proximal gastric cancer and esophagogastric cancer Study design: Clinical trial Study population: Patients with locally advanced proximal gastric cancer and esophagogastric cancer referred to Omid hospital of Mashhad. Inclusion criteria: All patients with locally advanced proximal gastric cancer and esophagogastric cancer who have positive biopsy results and has been filled the consent form informally. Exclusion criteria: Patients (illness) at stage I,IV - patient dissatisfaction- comorbid diseases that prevent oncologic treatment- previous cancer- previous chemotherapy or radiotherapy- hepatic and renal dysfunction that prevents oncologic treatments- Performance status 3,4 ECOG Intervention : All patients with locally advanced proximal gastric cancer and esophagogastric cancer that have positive biopsy result are considerated for receiving chemo radiation therapy before surgery. Before treatment, patients undergo a complete evaluation of metastatic spread. Measurements before treatment include: a full clinical examination, endoscopy and biopsy, endosonography, abdominal CT scan, chest radiography, complete blood tests including CBC, liver and renal function test. After criteria approval, eligible patients entered Preoperative Chemo radiation trial. Therapeutic regimen including: chemotherapy and radiation with capecitabin 625 mg/m2/bid as otherwise afford , 5 - fluorouracil 325 mg/m2 and leucovorin 20/mg2 at the first four days and the last three days of radiotherapy . Radiotherapy with a total dose of 4500 cgy with two fields AP-PA and with a fractions of 180 - 200 cgy done. During third to fourth week of treatment, blood test (CBC) is controlled (to control hematologic side effects) and also controlled before surgery. 4 - 6 weeks after completing Chemo radiation, patients are referred for surgery. After surgery, specimens are evaluated for pathologic response and resectability. The postoperative morbidity and mortality includes leakage is investigated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014072015044N1**
Registration date: **2014-07-20, 1393/04/29**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-07-20, 1393/04/29

Registrant information

Name
Soodabeh Shahidsales
Name of organization / entity
Cancer research center
Country
Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research,Mashhad University of Medical Sciences.

Expected recruitment start date

2012-03-20, 1391/01/01

Expected recruitment end date

2014-12-21, 1393/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial to evaluate the resectability rate and tumor response to neoadjuvant chemo radiotherapy in patients with locally advanced proximal gastric cancer and esophagogastric cancer.

Public title

Neoadjuvant chemoradiotheraphy in patients with locally advanced gastric cancer

Purpose

Treatment

Inclusion/Exclusion criteria

The main inclusion criteria: All patients with locally advanced proximal gastric cancer and esophagogastric cancer who have positive biopsy results and has been filled the consent form informally. The main exclusion criteria: patients (illness) at stage I and IV; patient dissatisfaction; comorbid diseases that prevent oncologic treatment; previous cancer; previous chemotherapy or radiotherapy; hepatic and renal dysfunction that prevents oncologic treatments; Performance status 3,4 ECOG

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Daneshgah st., Ghoreshi Building

City

Mashhad

Postal code

Approval date

2012-02-18, 1390/11/29

Ethics committee reference number

1

Health conditions studied

1

Description of health condition studied

Proximal gastric cancer

ICD-10 code

C16.1

ICD-10 code description

Fundus of stomach

2

Description of health condition studied

Gastro-oesophageal cancer

ICD-10 code

C16.0

ICD-10 code description

Gastro-oesophagea cancerl

Primary outcomes

1

Description

Evaluation of resectability rate and tumor response in patients with locally advanced proximal gastric cancer and esophagogastric cancer treated with neoadjuvant chemoradiotheraphy

Timepoint

Pathologic Evaluation of surgical specimen

Method of measurement

Pathologic response

Secondary outcomes

1

Description

Rate of surgical copmplication

Timepoint

Post operation

Method of measurement

Incisional leek,post op mortality

Intervention groups

1

Description

All patients with locally advanced proximal gastric cancer and junction esophagogastric cancer receive Preoperative Chemoradiation therapy before surgery are candidates with a positive biopsy . Before treatment , patients underwent a complete evaluation of metastatic spread , and are to be excluded . Measures before treatment included a full clinical examination , endoscopy and biopsy , Endosonography , abdominal CT , chest radiography , complete blood tests including CBC , liver and renal function test . After approval criteria , and the patients entered Trial Preoperative Chemoradiation placed. Drug regimens , including chemotherapy and radiation Capecitabin 625 mg/m2/Bid as otherwise afford , 5 - flourouracil 325 mg/m2 and locoverin20 mg /m2 of 4 first days and 3 last days of radiotherapy . Radiotherapy with a total dose of 4500 cgy with two field AP-PA with fractions 180 - 200 cgy done . Third to fourth week of treatment, blood tests (CBC) is controlled (to control hematologic effects) controlled blood testing before surgery . 4 -6 weeks after Chemoradiation patient is referred for surgery . After surgical pathology specimens of pathologic response and resection of the features represented. The morbidity and mortality of postoperative incisional surgery includes Leak is investigated.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashhad Omid Hospital

Full name of responsible person

Soodabeh Shahidsales

Street address

Omid Hospital, Koohsangi st. , Mashhad

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Mashhad University of Medical Sciences

Full name of responsible person

Zohreh Boostanian

Street address

Vice chancellor for research, Office building Qureshi, University st., Mashhad

City

Mashhad

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Omid Hospital

Full name of responsible person

Ali Emadi Torghabeh

Position

Assistant of radiation oncology

Other areas of specialty/work

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

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Position

Assistant Professor of Radiation Oncology

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty