Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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)

Phone

+98 51 1846 1518

Email address

shahidsaless@mums.ac.ir

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

Street address
Omid Hospital, Koohsangi st., Mashhad, Iran

City
Mashhad

Postal code

Phone
+98 51 1846 1518

Fax

Email
emadita1@mums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Cancer research center , Faculty of medicin, Mashhad University of Medical Sciences

Full name of responsible person
Soodabeh Shahidsales

Position
Assistant Professor of Radiation Oncology

Other areas of specialty/work

Street address
Cancer Research Center, Omid Hospital, Koohsangi st.,Mashhad, Iran

City
Mashhad

Postal code

Phone
+98 51 1846 1518

Fax

Email

shahidsaless@mums.ac.ir

Web page address

http://www.mums.ac.ir/cancer

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University OF Medical Sciences

Full name of responsible person

Ali Emadi Torghabeh

Position

Assistant

Other areas of specialty/work

Street address

Omid Hospital, Koohsangi st., Mashhad, Iran

City

Mashhad

Postal code

Phone

+98 51 1854 6084

Fax

Email

emadita1@mums.ac.ir

Web page address

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