# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 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**

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Omid Hospital, Koohsangi st., Mashhad, Iran

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**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

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## Person responsible for updating data

**Contact**

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**Full name of responsible person**

Ali Emadi Torghabeh

**Position**

Assistant

**Other areas of specialty/work**

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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*