

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of induction chemotherapy and Neoadjuvant chemoradiotherapy effect on pathologic complete response in cardia and gastric cancer

Protocol summary

Summary

In western studies, 5 years survival of complete resected stage gastric cancer is approximately 70_75 percent; while for stage II and more, this decreased to less than 35 percent. These findings have led to efforts to improve outcomes in these patients with employing adjuvant or neoadjuvant treatment. Recent studies have demonstrated that induction chemotherapy followed by concurrent Chemoradiotherapy provide constant survival period by significant pathologic response. However, there is no single standard treatment for gastric or cardiac cancer. In this pilot interventional study, 30 new patients with gastric cancer who would be referred to radiotherapy oncology centre in Emam Hossein hospital since 23 August 2017_ 22 September 2018 and have all inclusion criteria of our study will be imported to study. They will receive induction chemotherapy at first (paclitaxel 50 mg/m², carboplatin AUC=2, weekly for 12 courses), then concurrent neoadjuvant chemoradiotherapy (RT/Radiotherapy 45Gy/25 fractions, oxaliplatin 40mg/m² weekly and capecitabine 500mg/m²/BID daily during overall treatment time). After 6_8 weeks they will undergo surgery and the pathologic complete response will be assessed in surgical specimen. Pathologic complete response means no residue of carcinoma in cardia, stomach, esophageal gastric junction and regional lymph nodes. Also we'll consider age, family history of gastrointestinal cancer, tumor distance from incisor teeth by endoscopy, siweert type, TNM staging, Tumor histology and grade, surgical margin and pathologic complete response.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017100236514N1**

Registration date: **2017-10-16, 1396/07/24**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-10-16, 1396/07/24

Registrant information

Name

Payam Azadeh

Name of organization / entity

Shahid Beheshti Medical University, Emam Hossein hospital, clinical oncology department

Country

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Phone

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Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2017-08-23, 1396/06/01

Expected recruitment end date

2018-09-22, 1397/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of induction chemotherapy and Neoadjuvant

chemoradiotherapy effect on pathologic complete response in cardia and gastric cancer

IR.SBMU.MSP.REC.1396.353

Public title

Effect of chemotherapy and chemoradiotherapy on stomach cancer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: stomach or cardiac cancer; resectable locally advanced Tumor (T3 or T4 with pericardial or pleural or diaphragmatic involvement, or N1 and more); no metastasis; ages 18_75; normal liver and renal function test; performance status (ps) 0_1. Exclusion criteria: T1_2 N0, unresectable tumors(T4b); peritoneal or visceral metastasis; non regional lymph node extension such as paraaortic or mesenteric; age <18 or >75; impaired liver or renal function test and PS 2 and more.

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

N/A

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

School of Medicine, Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences, Velenjak, Chamran highway

City

Tehran

Postal code

Approval date

2017-08-08, 1396/05/17

Ethics committee reference number

Health conditions studied

1

Description of health condition studied

Gastric and cardiac cancer

ICD-10 code

C16

ICD-10 code description

Malignant neoplasm of stomach

Primary outcomes

1

Description

pathologic complete response

Timepoint

6_8 weeks after completion of them I radiotherapy, in surgical specimen

Method of measurement

microscopic assessment of surgical specimen by pathologist

Secondary outcomes

1

Description

surgical margin

Timepoint

after intervention, in surgical specimen

Method of measurement

microscopic assessment of surgical specimen by pathologist

Intervention groups

1

Description

They will receive induction chemotherapy at first (paclitaxel 50 mg/m², carboplatin AUC=2. weekly for 12 courses), then concurrent neoadjuvant chemoradiotherapy (RT/Radiotherapy 45Gy/25frc, oxaliplatin 40mg/m² weekly and capecitabine 500mg/m²/BID daily during overall treatment time). 6_8 weeks after completion of neoadjuvant treatment they will undergo surgery

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam hossein hospital

Full name of responsible person

Dr payam azadeh, radiation oncologist

Street address

Emam hossein squad, shahid madani avenue

City

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Afshin Zarghi

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Velenjak, Chamran highway**City**

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shahid Beheshti 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**Shahid Beheshti University of Medical Sciences,
Emam Hossein hospital**Full name of responsible person**

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Position

Radiation oncologist

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Person responsible for updating data**Contact****Name of organization / entity**Shahid Beheshti University of Medical Sciences,
Emam Hossein hospital**Full name of responsible person**

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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