Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Oct 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 stageI 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 follow 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 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/25frc، oxaliplatin 40mg/m2 weekly and capecitabin 500mg/m2/BID daily during overall tretment 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 caner, tumor distance from incisior teeth by endoscopy, sieweert type, TNM staging, Timor 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

Iran (Islamic Republic of)

Phone

+98 21 7734 3000

Email address

zeinab.abiar@sbmu.ac.ir

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

Public title
Effect of chemotherapy and chemoradiotherapyon stomach cancer
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: stomach or cardiac cancer; resectable locally advanced Timor (T3 or T4 with pricardial or pleural or diaphragmatic involvement, or N1 and more); no metastasis; ages 18_75; normal liver and renal function test; performance statues (ps) 0_1. Exclusion criteria: T1_2 N0, unresectable tumors(T4b); peritoneal or visceral metastasis; non regional lymph node extension such as paraaortic or mesantric; 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
IR.SBMU.MSP.REC.1396.353

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 capecitabin 500mg/m2/BID daily during overall tretment 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
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. Afshin Zarghi
Street address
Shahid Beheshti University of Medical Sciences, 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
Dr. Ali Yaghoobi jooybari
Position
Radiation oncologist
Other areas of specialty/work
Street address
Emam Hossein squad, Shahid Madani avenue
City
Tehran
Postal code
Phone
+98 21 73430
Fax
+98 21 7755 2056
Email
dryaghobii@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences, Emam Hossein hospital
Full name of responsible person
Dr. Payam Azadeh
Position
Radiation oncologist
Other areas of specialty/work
Street address
Emam Hossein square, shahid madani avenue
City
Tehran
Postal code
Phone
+98 21 73430
Fax
+98 21 7755 2056
Email
dr_azadeh@sbmu.ac.ir
Web page address
www.ehmc.ir

Person responsible for updating data

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences, Emam Hossein hospital
Full name of responsible person
Dr. Zeinab Abiar
Position
Radiation oncology resident
Other areas of specialty/work
Street address
Emam Hossein square, Shahid Madani avenue
City
Tehran
Postal code
Phone
+98 21 73430
Fax
+98 21 7755 2056
Email
zeinab.abiar@sbmu.ac.ir
Web page address
www.ehmc.ir

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