

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 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 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/m<sup>2</sup>, carboplatin AUC=2, weekly for 12 courses), then concurrent neoadjuvant chemoradiotherapy (RT/Radiotherapy 45Gy/25frc, oxaliplatin 40mg/m<sup>2</sup> weekly and capecitabin 500mg/m<sup>2</sup>/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 incisor teeth by endoscopy, siewert 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

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/m<sup>2</sup>, carboplatin AUC=2. weekly for 12 courses), then concurrent neoadjuvant chemoradiotherapy (RT/Radiotherapy 45Gy/25frc, oxaliplatin 40mg/m<sup>2</sup> weekly and capecitabin 500mg/m<sup>2</sup>/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**

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*