

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### **FLOT induction chemotherapy before neoadjuvant chemoradiotherapy and resectability and pathologic response in patients with esophagogastric junction and Proximal gastric adenocarcinomas**

#### **Protocol summary**

##### **Study aim**

Determining tumor removal rate and complete pathologic response after surgery for advanced adenocarcinoma of the esophagogastric junction and proximal stomach using induction chemotherapy FLOT before neoadjuvant chemoradiotherapy

##### **Design**

Patients receive two courses of FLOT chemotherapy before neoadjuvant concurrent chemoradiation. Simulation based on CT scan will be used to perform radiotherapy. Patients will be subjected to a CT scan of the thoracoabdominopelvic in the supine position. The protocol of concurrent chemotherapy with radiotherapy will be weekly Paclitaxel and Carboplatin during the radiotherapy period

##### **Settings and conduct**

Mashhad: Imam Reza Hospital, Department of Radio Oncology and Omid Hospital

##### **Participants/Inclusion and exclusion criteria**

log in: Appropriate performance status (ECOG score 0-1)  
Presence of pathologic diagnosis based on adenocarcinoma of the distal esophagus and the proximal stomach and the esophago-gastric junction  
Resectable malignant lesion  
log out: Presence of significant comorbidity  
History of collagen vascular disease  
Presence of metastatic disease in initial review  
History of previous chemotherapy or radiotherapy  
History of malignancy of solid organs during the last 5 years (except skin BCC/SCC and cervical CIN which were treated with surgery)  
Advanced inoperable cancer  
Pregnancy and breastfeeding

##### **Intervention groups**

Receiving 2 course of chemotherapy before concurrent neoadjuvant chemoradiotherapy

##### **Main outcome variables**

Resection of malignant lesion during surgery  
Tumor response to neoadjuvant therapy in pathology after

surgery

#### **General information**

##### **Reason for update**

##### **Acronym**

##### **IRCT registration information**

IRCT registration number: **IRCT20210706051800N1**

Registration date: **2022-09-19, 1401/06/28**

Registration timing: **prospective**

Last update: **2022-09-19, 1401/06/28**

Update count: **0**

##### **Registration date**

2022-09-19, 1401/06/28

##### **Registrant information**

##### **Name**

Zohre Pischevar

##### **Name of organization / entity**

##### **Country**

Iran (Islamic Republic of)

##### **Phone**

+98 51 3869 0835

##### **Email address**

pishevarfz971@mums.ac.ir

##### **Recruitment status**

**Recruitment complete**

##### **Funding source**

##### **Expected recruitment start date**

2022-09-23, 1401/07/01

##### **Expected recruitment end date**

2023-03-20, 1401/12/29

##### **Actual recruitment start date**

empty

##### **Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

FLOT induction chemotherapy before neoadjuvant chemoradiotherapy and resectability and pathologic response in patients with esophagogastric junction and Proximal gastric adenocarcinomas

**Public title**

effect of chemotherapy before chemoradiation on response rate

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Appropriate performance status(ECOG score 0-1)  
Presence of pathologic diagnosis based on adenocarcinoma of the distal esophagus and the proximal of stomach and the esophago-gastric junction  
Resectable malignant lesion(stage I B-III B)

**Exclusion criteria:**

Presence of significant comorbidity included uncontrolled diabetes mellitus, uncontrolled hypertension, history of ischemic heart disease and CABG, history of cerebrovascular accident(CVA), grade 2 or more neuropathy, failure of bone marrow(lymphopenia and leukopenia and thrombocytopenia in initial review), heart failure(EF ≤ 45%), renal dysfunction(GFR < 50 mg/m), hepatic dysfunction (AST/ALT ≥ 3 × ULN, Billi ≥ 1.5 × ULN) which prevents the prescription of neoadjuvant or surgery for the patient  
History of collagen vascular disease  
Presence of metastatic disease in initial review  
History of previous chemotherapy or radiotherapy  
History of malignancy of solid organs during the last 5 years( except skin BCC/SCC and cervical CIN which were treated with surgery  
Advanced inoperable cancer  
Pregnancy and breastfeeding

**Age**

From **18 years** old to **65 years** old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **40**

**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**

Medical Science university, Azadi Square

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9177948564

**Approval date**

2021-06-01, 1400/03/11

**Ethics committee reference number**

IR.MUMS.MEDICAL.REC.1400.153

**Health conditions studied****1****Description of health condition studied**

Locally advanced adenocarcinoma of the esophago gastric junction and proximal of the stomach

**ICD-10 code**

C16.0

**ICD-10 code description**

Malignant neoplasm of cardia

**Primary outcomes****1****Description**

Resection of malignant lesion during surgery

**Timepoint**

Post surgery based on pathologic report

**Method of measurement**

Based on residual tumor classification on including R0: lack of micro and macroscopic residue R1: microscopic residue and positive surgical margin and lack of gross residue R2: gross residue

**2****Description**

Tumor response to neoadjuvant therapy in pathology after surgery

**Timepoint**

Post surgery based on pathologic report

**Method of measurement**

Based on American Institute of pathology: 1) Complete response in the sense of the absence of tumoral cells in the primary location of the tumor and lymph nodes

- 2)partial response: presence of limited tumor remnants with fibrosis in the primary site and examined nodes and  
 3)No response:presence of tumoral cells in the primary location of the tumor and lymph nodes

## Secondary outcomes

### 1

#### Description

Complications of chemotherapy

#### Timepoint

During induction chemotherapy every 2 weeks and during chemoradiation weekly

#### Method of measurement

History,Physical exam, lab test include complete blood count and kidney function test and liver function test and complication of treatment based on Common Terminology Criteria for Adverse Events(CTCAE-EORTC)

### 2

#### Description

Complications of Radiotherapy

#### Timepoint

Weekly During Radiotherapy and then monthly

#### Method of measurement

Complication of treatment based on Common Terminology Criteria for Adverse Events(CTCAE-EORTC)

## Intervention groups

### 1

#### Description

Intervention group: In the intervention group, before neoadjuvant chemoradiotherapy, patients will undergo two cycles of chemotherapy with FLOT regimen (containing fluorouracil, leucovorin, oxaliplatin and docetaxel). Inpatient FLOT chemotherapy protocol with drugs oxaliplatin 85 mg/m<sup>2</sup> over two hours in dextrose water serum on the first day, Leucovorin 200 mg/m<sup>2</sup> over two hours in normal saline serum on the first day, docetaxel 50 mg/m<sup>2</sup> within one hour in normal saline serum on the first day and 5 fluorouracil 2600 mg/m<sup>2</sup> within 24 hours in normal saline serum on the first day [or if the treating physician sees fit, infusion of 1200 mg/m<sup>2</sup> daily within 48 hours]. To perform radiotherapy, simulation based on CT scan will be used. Patients will be subjected to a CT scan of the thorax and abdomen in the supine position. The chemotherapy protocol will be simultaneous with radiotherapy in the form of paclitaxel (50 mg/m<sup>2</sup> ) and carboplatin (AUC=2) weekly during the radiotherapy period.

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Reza Hospital, Radio Oncology Department

##### Full name of responsible person

Zohreh Pischevar

##### Street address

Ebne Sina St, The edge of Imam Reza square

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9188959986

##### Phone

+98 51 3854 3031

##### Email

pishevarfz971@mums.ac.ir

### 2

#### Recruitment center

##### Name of recruitment center

Omid Hospital

##### Full name of responsible person

Zohreh Pischevar

##### Street address

Alandasht Crossroads, Koohsangi Ave, Omid Hospital

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## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Full name of responsible person

Majid Ghayour Mobarhan

##### Street address

University of Medical Sciences, 3rd floor, University Research and Technology Vice-Chancellor, next to Hoizeh Cinema,University Ave

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GhayourM@mums.ac.ir

**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Mashhad University of Medical Sciences  
**Proportion provided by this source**  
100  
**Public or private sector**  
Public  
**Domestic or foreign origin**  
Domestic  
**Category of foreign source of funding**  
*empty*  
**Country of origin**  
**Type of organization providing the funding**  
Academic

## Person responsible for general inquiries

### Contact

**Name of organization / entity**  
Mashhad University of Medical Sciences  
**Full name of responsible person**  
Seyed Amir Aledavood  
**Position**  
Professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Radiotherapy  
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aledavooda@mums.ac.ir

## Person responsible for scientific inquiries

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## Person responsible for updating data

### Contact

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Medical doctor  
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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

### Justification/reason for indecision/not sharing IPD

The need to share non-identifiable personal data of patients is not felt individually, and it is sufficient to determine the benefits of the intervention performed in all patients or a subgroup of them with special characteristics.

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

No - There is not a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

### Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

### Title and more details about the data/document

The general demographic information of the patients will

be published by dividing them into specific subgroups, as well as the main and secondary outcomes of the study in each specific subgroup.

**When the data will become available and for how long**

After the publication of the article resulting from the study

**To whom data/document is available**

For researchers after obtaining permission from the subordinate authorities in the university

**Under which criteria data/document could be used**

To use the documents in similar academic studies and

after obtaining the necessary permits

**From where data/document is obtainable**

Vice President of Research and Technology of Mashhad University of Medical Sciences

**What processes are involved for a request to access data/document**

Sending the request to the research and technology vice-chancellor of the university and referring them to the director or research vice-chancellor of the radio-oncology department

**Comments**