

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 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

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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/m² over two hours in dextrose water serum on the first day, Leucovorin 200 mg/m² over two hours in normal saline serum on the first day, docetaxel 50 mg/m² within one hour in normal saline serum on the first day and 5 fluorouracil 2600 mg/m² within 24 hours in normal saline serum on the first day [or if the treating physician sees fit, infusion of 1200 mg/m² 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/m²) 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

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2

Recruitment center

Name of recruitment center

Omid Hospital

Full name of responsible person

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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

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

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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
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Latest degree
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Person responsible for updating data

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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