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

Determinig tumor removal rate and complete pathologic response after surgery for advanced adenocarcinoma of the esophagogastric junction and proximal stomach using induction chemotherpy 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 score0-1) Presence of pathologic diagnosis based on adenocarcinoma of the distal of esophagus and the proximal of stomach and the esophago-gastric junction Resectable malignant lesion log out: Presence of siginificant 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 Pishevar

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 befor chemoradiation on response rate

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Appropriate performance status(ECOG score0-1)
Presence of pathologic diagnosis based on adenocarcinoma of the distal of esophagus and the proximal of stomach and the esophago-gastric junction
Resectable malignant lesion(stageIB-IIIB)

Exclusion criteria:
Presence of siginificant comorbidity included uncontrolled diabetus 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 و Billt≥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 proxmimal 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
ļased 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 Institue 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 Pishevar
Street address
Ebne Sina St, The edge of Imam Reza square
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Phone
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Email
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2

Recruitment center
Name of recruitment center
Omid Hospital
Full name of responsible person
Zohreh Pishevar
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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Omid Hospital, Alandasht Crossroads, Koohsangi Ave
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Person responsible for scientific inquiries

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Name of organization / entity
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Full name of responsible person
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Position
Professor
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Specialist
Other areas of specialty/work
Radiotherapy
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Person responsible for updating data

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Zohreh Pishevar
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Radiotherapy
Street address
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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