Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of resectability rate and tumor complete pathological response in patients with locally advanced proximal gastric cancers receiving neoadjuant chemoradiothrapy

Protocol summary

Summary

This trial aims to evaluate the complete pathological tumor response and resectability rate in patients with locally advanced proximal gastric cancer and gastroesophageal cancer after concurrent chemoradiotherapy before surgery. Major conditions for entry into the study include performance status 0, 1 and 2; surgery in future treatment planning; and good condition for chemotherapy, radiotherapy and surgery. Exclusion criteria involve metastasis and death. The sample size is 40, and the study is in Phase 2 with no randomization. Patients are selected from Omid and Imam Reza hospitals in Mashhad. Patients undergo complete CT scan of the abdomen and pelvis to confirm the absence of metastasis. Following this, induction chemotherapy is administered with Paclitaxel 50 milligram/square meters/weekly and Carboplatin AUC=2 on a weekly basis for 3 to 6 weeks. Then, the patients will continue chemotherapy with the same protocol along with radiotherapy with a total dose of 45 Gray for 4 weeks. They will be subjected to total gastrectomy after the end of the combined treatment protocol. The primary outcome is resectability rate and complete pathological tumor response. In addition, myelosuppression, nausea, vomiting, and hair loss are examined.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017070834945N1**
Registration date: **2017-08-12, 1396/05/21**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-08-12, 1396/05/21

Registrant information

Name
Masume Masoudian
Name of organization / entity
Mashhad University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for Research, Mashhad University of Medical Sciences

Expected recruitment start date

2016-01-01, 1394/10/11

Expected recruitment end date

2019-01-01, 1397/10/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of resectability rate and tumor complete pathological response in patients with locally advanced proximal gastric cancers receiving neoadjuant chemoradiothrapy

Public title

Neoadjuant chemoradiothrapy in treatment of proximal gastric cancer

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: performance status 0, 1 and 2; surgery in future treatment planning; and good condition for chemotherapy, radiotherapy and surgery. Exclusion criteria: metastasis; death.
Age
No age limit
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
Vice-chancellery for Research, Mashhad University of Medical Sciences, Imam Khomaini St.,
City
Mashhad
Postal code
Approval date
2017-05-03, 1396/02/13
Ethics committee reference number
ir.mums.fm.rec.1396.03

Health conditions studied

1

Description of health condition studied
Gastric cancer
ICD-10 code
C16.9
ICD-10 code description
Stomach, unspecified

Primary outcomes

1

Description
Resectability of tumor or R0 resection
Timepoint
After 15 weeks of neoadjuant therapy
Method of measurement
Pathology report after surgery

Secondary outcomes

1

Description
Myelosuppression
Timepoint
every 7 days during treatment
Method of measurement
complete blood count

2

Description
Nausea
Timepoint
On a weekly basis
Method of measurement
Based on the scale provided by Common Terminology Criteria for Adverse Events, Version 4

3

Description
Vomiting
Timepoint
On a weekly basis
Method of measurement
Based on the scale provided by Common Terminology Criteria for Adverse Events, Version 4

4

Description
Hair loss
Timepoint
On a weekly basis
Method of measurement
Based on the scale provided by Common Terminology Criteria for Adverse Events, Version 4

Intervention groups

1

Description
Intervention Group (Concurrent chemoradiotherapy plus surgery): Patients undergo complete CT scan of the abdomen and pelvis to confirm the absence of

metastasis. Following this, induction chemotherapy is administered with Paclitaxel 50 milligram/square meters/weekly and Carboplatin AUC=2 on a weekly basis for 3 to 6 weeks. Then, the patients will continue chemotherapy with the same protocol along with radiotherapy with a total dose of 45 Gray for 4 weeks. They will be subjected to total gastrectomy after the end of the combined treatment protocol.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Omid Hospital

Full name of responsible person

Dr Masume Masoudian

Street address

Kuhsangi Ave., No. 10,

City

Mashhad

2

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Dr Masume Masoudian

Street address

Daneshgah Ave.,

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellery for Research and Technology, Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

Street address

Mashhad University of Medical Sciences, Daneshgah Ave.,

City

Mashhad

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice-chancellery for Research and Technology, Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Masume Masoudian

Position

Radiation Oncology Resident

Other areas of specialty/work

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+98 51 3509 8885
Fax
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Web page address

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