

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of total neoadjuvant multidrug chemotherapy including fluorouracil, leucovorin, oxaliplatin and docetaxel on pathologic complete response resectable locally advanced gastric adenocarcinoma

Protocol summary

Study aim

To determine the complete pathologic response rate following complete neoadjuvant chemotherapy in patients with resectable locally advanced gastric adenocarcinoma

Design

Phase 2 single group clinical trial without blinding, without randomization and without parallel group on 63 patients.

Settings and conduct

This single arm clinical trial will be performed in the oncology radiotherapy ward of Namazi Hospital. In this study, patients with operable gastric cancer will be assigned to the intervention group to receive complete neoadjuvant chemotherapy.

Participants/Inclusion and exclusion criteria

In this single arm study, patients with pathologically confirmed gastric adenocarcinoma in biopsy, perigastric lymph node metastasis in CT scan and resectable primary gastric tumor based on CT scan and main exclusion criteria are no distant metastasis at the presentation, previous history of chemotherapy, previous history of radiotherapy, previous history of malignancy, suffering from uncontrolled diabetes mellitus and uncontrolled hypertension and no consent to enroll

Intervention groups

Patients will be treated with complete neoadjuvant chemotherapy.

Main outcome variables

Pathological response, surgical margin status and treatment side effects

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211211053356N1**

Registration date: **2022-01-21, 1400/11/01**

Registration timing: **registered_while_recruiting**

Last update: **2022-01-21, 1400/11/01**

Update count: **0**

Registration date

2022-01-21, 1400/11/01

Registrant information

Name

Mehrdad Golmoradi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 4332

Email address

mehrdadg239@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-21, 1400/11/01

Expected recruitment end date

2023-03-21, 1402/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of total neoadjuvant multidrug chemotherapy including fluorouracil, leucovorin, oxaliplatin and docetaxel on pathologic complete response resectable

locally advanced gastric adenocarcinoma	
Public title	Total neoadjuvant multidrug chemotherapy in the management of gastric cancer
Purpose	Treatment
Inclusion/Exclusion criteria	
Inclusion criteria:	Pathologically confirmed gastric adenocarcinoma in biopsy Perigastric lymph node metastasis in CT scan Resectable primary gastric tumor based on CT scan
Exclusion criteria:	Presence of distant metastasis at the presentation Previous history of chemotherapy Previous history of radiotherapy Previous history of malignancy Suffering from uncontrolled diabetes mellitus Suffering from uncontrolled hypertension No consent to enroll
Age	From 18 years old to 70 years old
Gender	Both
Phase	2
Groups that have been masked	No information
Sample size	Target sample size: 63
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	
<u>1</u>	
Ethics committee	
Name of ethics committee	Research Ethics Committees of School of Medicine - Shiraz University of Medical Sciences
Street address	Zand St., Imam Hossein Sq., Shiraz Medical School
City	Shiraz
Province	Fars
Postal code	7134845794
Approval date	2021-08-19, 1400/05/28

Ethics committee reference number	IR.SUMS.MED.REC.1400.264
Health conditions studied	
<u>1</u>	
Description of health condition studied	Gastric cancer
ICD-10 code	C16.9
ICD-10 code description	Malignant neoplasm of stomach, unspecified
Primary outcomes	
<u>1</u>	
Description	Pathologic response
Timepoint	After the intervention and providing the pathologic report of gastrectomy
Method of measurement	Based on report of pathologist
Secondary outcomes	
<u>1</u>	
Description	Surgical margin status
Timepoint	After the intervention and providing the pathologic report of gastrectomy
Method of measurement	Based on pathologist report
<u>2</u>	
Description	Treatment completion rate
Timepoint	During the intervention, every three week
Method of measurement	History taking
<u>3</u>	
Description	Treatment toxicity
Timepoint	During the intervention, every three week
Method of measurement	history taking
Intervention groups	
<u>1</u>	
Description	

Intervention group: In total neoadjuvant chemotherapy group, patients will be treated with eight sessions of fluorouracil, leucovorin, oxaliplatin, and docetaxel before surgery. Fluorouracil as a 24-hour intravenous infusion at a dose of 2600 mg per body surface area on the first day, leucovorin as a 1-hour intravenous infusion at a dose of 200 mg per body surface area on the first day, oxaliplatin as a 1-hour intravenous infusion at a dose of 85 mg per body surface area on the first day and docetaxel as a 2-hour intravenous infusion at a dose of 50 mg per body surface area on the first day will be administered. Chemotherapy will be performed every 2 weeks in 8 sessions.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Namazi Hospital

Full name of responsible person

Mansour Ansari

Street address

Zand Street, Namazi Square

City

Shiraz

Province

Fars

Postal code

7193613311

Phone

+98 71 3647 4332

Email

nemazee_inf@sums.ac.ir

Web page address

<https://namazi.sums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mahtab Memarpour

Street address

Zand St., the central building of Shiraz University of Medical Sciences, the seventh floor

City

Shiraz

Province

Fars

Postal code

7134814336

Phone

+98 71 3212 2430

Email

vcrdep@sums.ac.ir

Web page address

<https://research.sums.ac.ir/Page-ResearchM/fa/205>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Mehrdad Golmoradi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Radiotherapy

Street address

Radiation Oncology ward, Nemazee Teaching Hospital, Namazi Sq., Zand Ave.

City

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Postal code

7134814336

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mehrdadg239@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

After the consent of the scientific officer and the
approval of the ethics committee, all data is potentially
shareable after unidentified individuals

When the data will become available and for how long

Access period starts 6 months after the results are
published

To whom data/document is available

Study data will be available only to researchers working
in academic and scientific institutions.

Under which criteria data/document could be used

The results of this study can be used for pooled meta-
analysis.

From where data/document is obtainable

The data can be accessed by correspondence with the
scientific officer. Address: Radiation Oncology ward,
Nemazee Teaching Hospital, Namazi Sq., Zand Ave.
Shiraz, Fars. 7134814336. Iran Phone +98 71 3647 4332
Cellphone +98 921 165 5956 Fax +98 71 3647 4326 E-
mail address mehrdadg239@gmail.com

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

After the consent of the scientific officer and the
approval of the ethics committee, all data is potentially
shareable after unidentified individuals

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

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