

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

1

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

1

Description of health condition studied

Gastric cancer

ICD-10 code

C16.9

ICD-10 code description

Malignant neoplasm of stomach, unspecified

Primary outcomes

1

Description

Pathologic response

Timepoint

After the intervention and providing the pathologic report of gastrectomy

Method of measurement

Based on report of pathologist

Secondary outcomes

1

Description

Surgical margin status

Timepoint

After the intervention and providing the pathologic report of gastrectomy

Method of measurement

Based on pathologist report

2

Description

Treatment completion rate

Timepoint

During the intervention, every three week

Method of measurement

History taking

3

Description

Treatment toxicity

Timepoint

During the intervention, every three week

Method of measurement

history taking

Intervention groups

1

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

Shiraz

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7134814336

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+98 71 3647 4332

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mehrdadg239@gmail.com

Person responsible for scientific inquiries

Contact

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Shiraz University of Medical Sciences

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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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