

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

To compare disease free survival between conventional method and chemotherapy before surgery in patient with gastric cancer.

Protocol summary

Summary

The objective of this study is to investigate disease free survival of patients with gastric cancer who are treated with surgery then chemoradiotherapy or vice versa. In this phase III clinical trial, patients with primary gastric cancer are randomly assigned to undergo surgery and then receive chemoradiotherapy or receive chemoradiotherapy and then surgery. After that, the patients in both groups receive chemotherapy for 3-4 times. All patients are visited frequently during the study period and any adverse effects will be recorded. Response to treatment is evaluated by post operative pathology and disease free survival time is measured by systematic follow-ups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138901111155N7**
Registration date: **2010-09-10, 1389/06/19**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2010-09-10, 1389/06/19

Registrant information

Name

Farahnaz Joukar

Name of organization / entity

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Gastrointestinal and liver disease Research Center

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Recruitment status

Recruitment complete

Funding source

Gastrointestinal and Liver Diseases Research Center

Expected recruitment start date

2010-07-06, 1389/04/15

Expected recruitment end date

2013-07-23, 1392/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

To compare disease free survival between conventional method and chemotherapy before surgery in patient with gastric cancer.

Public title

To compare disease free survival of patient with gastric cancer between 2 treatment regimens.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Primary gastric cancer in non cardiac area, No distant metastasis, Age less than 70 years old, Normal CBC (Hb>10, Plt>100/000, WBC>4000, PMN>1500), normal liver and kidney function, Satisfaction of patients to do this treatment, Conformance of surgeon for operation, No excessive changes in patients' weight, Carnofski criteria>70
Exclusion criteria: History of other cancers (instead of non melanocytic cancer of skin, History of major medical diseases (Intensive heart and/or lung disease)

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 50

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Gastrointestinal and Liver Diseases Research Center

Street address

Gastrointestinal and Liver Diseases Research Center-
Razi hospital - Sardar Jangal Ave-Rasht-Iran

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4144895655

Approval date

2009-11-11, 1388/08/20

Ethics committee reference number

148

Health conditions studied**1****Description of health condition studied**

Gastric cancer

ICD-10 code

C16.9

ICD-10 code description

Malignant neoplasm of stomach, Stomach, unspecified
Stomach

Primary outcomes**1****Description**

Response to neoadjuvant therapy

Timepoint

After surgery; every month until 3 months, every 3 months until 6 months and every 6 months until 36 months.

Method of measurement

pathological report

2**Description**

Disease free time

Timepoint

Every month until 3 months, every 3 months until 6 month, every 6 month until the end of follow up

Method of measurement

In years, pathologic results during the follow-ups

Secondary outcomes**1****Description**

Side effects of the treatment

Timepoint

Every month until 3 months, every 3 months until 6 months, every 6 months until the end of follow up

Method of measurement

Interview and physical exam

Intervention groups**1****Description**

In neo-adjuvant group (Cases); patients receive chemotherapy (Cisplatin 20mg/m² and 5FU 325mg/m²) and simultaneous abdomen and stomach Cobalt radiotherapy before radical surgery of the stomach. Finally, they receive ECX regimen; Xeloda (Capecitabin 625 mg) twice a day and Epirubicin 50 mg/m² for 2 weeks.

Category

Treatment - Drugs

2**Description**

In adjuvant group (Controls); patients undergo radical surgery then receive chemotherapy (Leukotrien 30mg/m² for 4 days and 5FU 325mg/m²) and abdomen and stomach Cobalt radiotherapy in the first and last weeks, and after that receive 3-4 periods of ECX. ECX regimen contains; Xeloda (Capecitabin 625 mg) twice a day and Epirubicin 50 mg/m² for 2 weeks.

Category

Other

Recruitment centers**1****Recruitment center**

Name of recruitment center

Gastrointestinal and Liver Diseases Research Center

Full name of responsible person

Professor Fariborz Mansour-Ghanaei

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Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

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Grant name**Grant code / Reference number**

152

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

Yes

Title of funding source

Gastrointestinal and Liver Diseases Research Center

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**

Gastrointestinal and Liver Diseases Research Center

Full name of responsible person

Farahnaz Joukar

PositionAssistant of Gastrointestinal and Liver Diseases
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Full name of responsible person

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Position

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empty
Clinical Study Report
empty
Analytic Code

empty
Data Dictionary
empty