Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of neoadjuvant chemotherapy in patients with gastric cancer referred to the oncology clinic of Imam Khomeini Hospital of Ardabil

Protocol summary

Summary

Check the benefits of preoperative chemotherapy in the treatment of patients with gastric cancer; Effects of preoperative chemotherapy regimens in selected patients; Surgical complications in patients receiving neoadjuvant chemotherapy; Clinical response (stage clinical) to chemotherapy prior to surgery; Pathological response (stage pathological) to chemotherapy prior to surgery; The response to neoadjuvant chemotherapy according to age and sex. Neoadjuvant chemotherapy is given in 3 preoperational periods. Choice regime was Ajani (taxotere 80 mg/m2, Cisplatin 70 mg/m2, 5-FU 750 mg/m2). After chemotherapy, the patient's CT scan was performed again and patients who have had a partial response or stable condition, surgery were performed. After surgery, the samples were sent for pathologic assessment. Patients received 3 courses of chemotherapy just as the same regimen before surgery. Inclusion criteria: diagnosis of gastric cancer; stage 2 and 3 gastric cancer; surgical patient; age 18-75 years old. Exclusion criteria: the patient's unwillingness to participate in the study; age over 75 years old; the underlying conditions; gastric cancer in stages 1 and 4; the recent history of chemotherapy or radiotherapy; performance state less than 70 Karnofsky score.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015020220906N1**
Registration date: **2015-02-15, 1393/11/26**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-02-15, 1393/11/26

Registrant information

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Name of organization / entity
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Recruitment status

Recruitment complete

Funding source
Ardabil University of Medical Sciences

Expected recruitment start date

2015-01-20, 1393/10/30

Expected recruitment end date

2015-06-21, 1394/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of neoadjuvant chemotherapy in patients with gastric cancer referred to the oncology clinic of Imam Khomeini Hospital of Ardabil

Public title

Effect of neoadjuvant chemotherapy in patients with gastric cancer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: diagnosis of gastric cancer; stage 2 and 3 gastric cancer; surgical patient; age 18-75 years old.

Exclusion criteria: the patient's unwillingness to participate in the study; age over 75 years old; the underlying conditions; gastric cancer in stages 1 and 4; the recent history of chemotherapy or radiotherapy; performance state less than 70 Karnofsky score.

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

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

Ardabil University of Medical Sciences

Street address

Ardabil University of Medical Sciences, Daneshgah street, Near Shurabil Lake

City

Ardabil

Postal code

Approval date

2013-07-14, 1392/04/23

Ethics committee reference number

Arums.REC.92.14

Health conditions studied

1

Description of health condition studied

Gastric cancer

ICD-10 code

C16

ICD-10 code description

Malignant neoplasm of stomach

Primary outcomes

1

Description

TNM staging

Timepoint

Before and after chemotherapy

Method of measurement

TNM staging and questionnaire

Secondary outcomes

1

Description

Neoadjuvant chemotherapy side effects

Timepoint

Before surgery

Method of measurement

Questionnaire

Intervention groups

1

Description

The regime Ajani (Taxoter 80mg / m2 - cisplatin 70mg / m2 and 5FU 750mg / M2) are used before and after chemotherapy

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ardabil Emam Khomeini hospital

Full name of responsible person

Ali Hossein Samadi- internal medicine, resident

Street address

Ardabil Emam Khomeini hospital, Gafur Jeddi street

City

Ardabil

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for Research and Technology

Full name of responsible person

Shahram Habibzadeh

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Emam Khomeini Hospital

City

Ardabil

Grant name

Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for Research and Technology
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

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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