

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 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

Name

Ali Hossein Samadi Takaldani

Name of organization / entity

Ardabil University of Medical Sciences and Health Services

Country

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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

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for Research and Technology

Full name of responsible person

Shahram Habibzadeh

Street address

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****Contact****Name of organization / entity**

Emam Khomeini Hospital of Ardabil

Full name of responsible person

Ali Hossein Samadi

Position

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Full name of responsible person

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Position

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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*