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 preoperative 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: empty
Update count: 0
Registration date 2015-02-15, 1393/11/26

Registrant information
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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

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
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    Emam Khomeini Hospital of Ardabil
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    Ali Hossein Samadi
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    MD, internal medicine resident
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Person responsible for scientific inquiries

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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