Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jul 2026

Effect of Neoadjuvant Chemoradiotherapy on Downstaging of Locally Advanced Cancer of Cardia and patient's survival

Protocol summary

Study aim

Due to the novelty of using neoadjuvant chemoradiotherapy in advanced localized cardia tumor to reduce the stage of the disease and the few studies that have been done in this field, this study designed to investigate the effect of neoadjuvant chemoradiotherapy in reducing the disease stage of cardia tumor. Evaluation of the outcomes performed before and after the intervention.

Design

This study is a single arm clinical trial that will be performed on 60 patients. The outcome will be assessed before and after the intervention and evaluated by the blinded assessment team.

Settings and conduct

This clinical trial will be performed in Imam Reza AS Hospital in Tabriz on the patients with a diagnosis of cardia cancer and tumor staging will be done. After the intervention, the effect of chemoradiotherapy on reducing the stage of tumor will be evaluated. Blinding will be performed for researchers assessing the stage of the disease before and after the intervention.

Participants/Inclusion and exclusion criteria

All patients with a diagnosis of cardia with Inclusion criteria: Patients aged 80-18 years Confirmation of advanced localized cardiac adenocarcinoma Not receiving previous chemotherapy and radiotherapy Suitable kidney, liver and bone marrow function Performance status less than equal 2 Non-inclusion criteria: Distant metastasis Patient dissatisfaction with neoadjuvant mototherapy Peritoneal carcinoma

Intervention groups

Chemotherapy regimen used in FC patients (5-fluorouracil 800 mg/m2 intravenously, continuous intravenous infusion for 24 hours daily on days 1 to 5 and cisplatin 15 mg/m2 intravenously, daily injection on days 1 to 5 for two courses It will be every 21 days. The patients will be treated for 25 sessions of 45Gy radiotherapy for 2 minutes, high energy - 18 mV.

Main outcome variables

The tumor staging before and after chemoradiotherapy.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140203016473N12**
Registration date: **2021-02-07, 1399/11/19**
Registration timing: **registered_while_recruiting**

Last update: **2021-02-07, 1399/11/19**
Update count: **0**

Registration date

2021-02-07, 1399/11/19

Registrant information

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Farzad Kakaei
Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-20, 1399/02/01

Expected recruitment end date

2021-04-21, 1400/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Neoadjuvant Chemoradiotherapy on Downstaging of Locally Advanced Cancer of Cardia and patient's survival

Public title

Effect of chemoradiotherapy on locally advanced cancer of Cardia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients aged between 18 to 80 years old Confirmed advanced localized cardiac adenocarcinoma (stage T3, T4, T2 with lymph node involvement) No history of previous chemotherapy and radiotherapy Proper function of the kidney (serum creatinine ≤ 1.5 mg / dl) Proper function of the liver (serum bilirubin ≤ 1.5 mg / dl) Proper function of the bone marrow (neutrophil count> 1500 per microliter, platelet count> 100 thousand and Hb> 10) Performance Status ≤ 2

Exclusion criteria:

Distant metastasis Patient dissatisfaction with neoadjuvant therapy Stages T1 and T2 without lymph node involvement (according to the AJCC staging system) Peritoneal carcinoma

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

The outcome assessor who is responsible for assessing the stage of the disease before and after the intervention (using the results of radiological reports) will be blinded to whether the intervention was performed on patients (before or after the intervention).

Placebo

Not used

Assignment

Single

Other design features

In this study, all patients with cardiac cancer diagnosis will be examined for the stage of tumor before and after receiving chemoradiotherapy .

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Imam Reza (AS) Hospital, Golgasht Ave.

City

Tabriz

Province

East Azarbaijan

Postal code

5158646978

Approval date

2020-09-14, 1399/06/24

Ethics committee reference number

IR.TBZMED.REC.1399.620

Health conditions studied

1

Description of health condition studied

Cardia cancer

ICD-10 code

C16.0

ICD-10 code description

Malignant neoplasm of cardia

Primary outcomes

1

Description

The stage of cardiac cancer after chemoradiotherapy intervention

Timepoint

4 to 6 weeks after the intervention

Method of measurement

Staging of heads based on Tumor, Node, Metastases (TNM) system

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients on FC diet containing 5-fluorouracil 800 mg / m2 intravenously (Alhavi Pharmaceutical Co.), continuous intravenous infusion for 24 hours daily on days 1 to 5 and cisplatin 15 mg / m2

intravenously (Sobhan Oncology Pharmaceutical Co.), daily injection on days 1 to 5 for two periods Every 21 days with 25 sessions of 45Gy radiotherapy for 2 minutes, high energy - 18 mV

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital, Tabriz University of Medical Sciences

Full name of responsible person

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Sponsors / Funding sources

1

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

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Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available