

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

A survey on different chemoradiation of esophageal cancer with cisplatin and irrinotecan compered with paclitaxol /carboplatin and evaluation of their effect and toxicity

Protocol summary

Summary

In this prospective randomized study, patient with squamous cell carcinoma or adenocarcinoma of esophagus or cardia and no distant metastasis, candidate for infinitive chemoradiation are taking part. Methods: In arm 1 (one arm) radiotherapy begins 3weeks after induction chemotherapy with combination regimes Cispelatin 30mg/m2 and Irrinotecan 65mg/m2 days 1 and 8.In same chemotherapy protocol continue, day 1 and 8, and 29 and 35, during the 5 weeks 5040CGry radiotherapy program. Afterward, patients in the arm complete their treatment program with two courses of three weekly apart of the same chemotherapy regimens.In the arm two (another arm) patients are treated with weekly paclitaxol 50mg/m and carboplatin (AUC:2) during a 5 weeks ,5040CGray radiotherapy program.Patients followed up and the toxicity of treatment in both arms and DFS and OS are evaluated. Inclusion criteria:Primery Esophageal or Cardioesooophageal Cancer(Adenocarcinoma or Scc);Without eny distant metastas;Maximum age 75 years ;Performance Status>70% ;Hemotologically Stable; Normal liver and kidney function; Patient Satisfaction; Unfit patient for surgery. Exclusion Criteria;Metastatic disease; Cervical Esophageal Cancer; Thracheoesophageal fistula; Another previous or current malignant disease ; Any surgery performed within the past 4 weeks; According to the judgment of physition. Primary outcome:Survival Rate Secondary outcome:Disease Free Survival -toxicity

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014110219783N1**
Registration date: **2017-07-24, 1396/05/02**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-07-24, 1396/05/02

Registrant information

Name

Mitra Fazl Ersi

Name of organization / entity

Mashhad University Of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 51 3846 1516

Email address

fazlm1@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2016-05-12, 1395/02/23

Expected recruitment end date

2018-05-13, 1397/02/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A survey on different chemoradiation of esophageal cancer with cisplatin and irrinotecan compered with paclitaxol /carboplatin and evaluation of their effect and

toxicity

Public title

Effect of definitive chemoradiation with cisplatin-irrinotecan or carboplatin-paclitaxol in esophageal cancer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Primary Esophageal or Cardioesophageal Cancer (Adenocarcinoma or Scc); Without any distant metastases; Maximum age 75 years; Performance Status > 70%; Hematologically Stable; Normal liver and kidney function; Patient Satisfaction; Unfit patient for surgery. Exclusion Criteria: Metastatic disease; Cervical Esophageal Cancer; Tracheoesophageal fistula; Another previous or current malignant disease; Any surgery performed within the past 4 weeks; According to the judgment of physician.

Age

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

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary IDs

1

Registry name

-

Secondary trial ID

-

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Regional committee of Mashhad University of Medical Ethics

Street address

Goreishi Building, Daneshgah Street

City

Mashhad

Postal code

Approval date

2016-05-21, 1395/03/01

Ethics committee reference number

IR.MUMS.fm.REC.1394.85

Health conditions studied

1

Description of health condition studied

Chemoradiation Protocols

ICD-10 code

C15.1-C15.

ICD-10 code description

مری توراسیک_مری شکمی_کاردیا

Primary outcomes

1

Description

Survival Rate

Timepoint

1-Every 3 months after start of intervention 2-Following every cycle of chemotherapy

Method of measurement

1-Months that patients survive after intervention 2-Questionnaire

Secondary outcomes

1

Description

1-Disease Free Survival 2-toxicity

Timepoint

1-Every 3 months after start of intervention 2-Following every cycle of chemotherapy

Method of measurement

Months that patients survive after start of intervention-questionnaire

Intervention groups

1

Description

Patients in the arm 1 treat with the combination of cisplatin 30mg/m² and irrinotecan 65mg/m² days 1,8 every 3 weeks at least 2 cycles during radiotherapy and 1 cycle before and 2 cycles after chemoradiotherapy. Chemotherapy cycles are prescribed: platelets > 85000, Hb 8mg/dl, GFR > 40 and liver function tests no more than 1.5 times the normal. Radiotherapy course compose 50,40CGy during 5-6 weeks.

Category

Treatment - Drugs

2

Description

Patient in the control arm treated with the combination of paclitaxel 50mg/m² and carboplatin AUC:2, weekly during radiotherapy.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person

Mitra Fazl Ersi

Street address

Emam Reza Square

City

Mashhad

2

Recruitment center

Name of recruitment center

Omid Hospital

Full name of responsible person

Mitra Fazl Ersi

Street address

Kohsangy Street, Alandasht Square

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Mashhad University of Medical Sciences

Full name of responsible person

Marjan Ardakanian

Street address

Ghoreishi Building, Daneshgah Street

City

Mashhad

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, Mashhad University of Medical Sciences

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

Cancer Research Center

Full name of responsible person

Mitra Fazl Ersi

Position

Radiotherapy And Oncology

Other areas of specialty/work

Street address

Omid Hospital, Alandasht Square, Kohsangy Street

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fazlm1@mums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

University Of Medical Sciences

Full name of responsible person

Roham Salek

Position

Associate Professor Of Radiotherapy & Oncology

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

Name of organization / entity

Cancer Research Center

Full name of responsible person

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Position

Radiotherapy and Oncology

Other areas of specialty/work

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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