

# 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/m<sup>2</sup> and irrinotecan 65mg/m<sup>2</sup> 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/m<sup>2</sup> 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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**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

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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*