

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Jun 2026

### Comparison of the efficacy and the toxicity of two chemoradiation protocols of cisplatin-irinotecan and carboplatin-paclitaxol, in operable esophageal cancer.

#### Protocol summary

##### Study aim

The purpose of this study is to evaluate the preoperative chemo-radiation of esophageal cancer with Cisplatin-Irinotecan compared with Paclitaxol/Carboplatin.

##### Design

Two arm parallel groups randomized trial of preoperative chemoradiation among 100 patients with esophageal cancer

##### Settings and conduct

In one arm radiotherapy begins 3 weeks after induction chemotherapy with combination of cisplatin 30 mg per square metre and irinotecan 65 mg per square metre, days 1 and 8. The same chemotherapy protocol continue, day 1 and 8, and 29 and 35, during the 5 weeks of 5040 cGy radiotherapy program. In the arm two patients are treated with weekly paclitaxol 50 mg per square metre and carboplatin with AUC 2 during the same 5 weeks 5040 cGy radiotherapy program. Then, patients undergo surgery in both groups. After surgery, patients in the arm1, complete their treatment program with two courses of the same chemotherapy regimens while patients in the arm 2 are followe without any chemotherapy.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: primary esophageal cancer (adenocarcinoma or squamous cell carcinoma); no distant metastasis; maximum age 75 years; performance Status > 70%; stable hematological status; normal liver and kidney function; patient consent; suitable patient for surgery. Exclusion Criteria: metastatic disease; cervical esophageal cancer; thraceo-esophageal fistula; another previous or current malignant disease; any major surgery within the past 4 weeks.

##### Intervention groups

Chemotherapy with the combination of cisplatin 30 mg per square metre and irinotecan 65 mg per square metre on days 1 and 8 every 3 weeks at least 2 cycles during

radiotherapy and at most 3 cycles before surgery.

##### Main outcome variables

Survival Rate

#### General information

##### Reason for update

##### Acronym

Mashhad Esophageal Cancer Treatment Study01

##### IRCT registration information

IRCT registration number: **IRCT20141102019783N5**

Registration date: **2022-02-06, 1400/11/17**

Registration timing: **retrospective**

Last update: **2022-02-06, 1400/11/17**

Update count: **0**

##### Registration date

2022-02-06, 1400/11/17

##### 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

support by deputy of research

##### Expected recruitment start date

2015-06-22, 1394/04/01

##### Expected recruitment end date

2019-03-20, 1397/12/29  
**Actual recruitment start date**

2015-06-22, 1394/04/01

**Actual recruitment end date**

2021-03-19, 1399/12/29

**Trial completion date**

2021-03-19, 1399/12/29

**Scientific title**

Comparison of the efficacy and the toxicity of two chemoradiation protocols of cisplatin-irinotecan and carboplatin-paclitaxol, in operable esophageal cancer.

**Public title**

Preoperative chemoradiation with cisplatin-irinotecan compared with carboplatin-paclitaxel in esophageal cancer.

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Primary esophageal cancer(adenocarcinoma or squamous cell carcinoma) No distant metastasis  
Maximum age 75 years Performance Status>70% Stable hematologic status Normal liver and kidney function  
Patient consent suitable for surgery Exclusion Criteria:  
Metastatic disease Cervical Esophageal Cancer  
Thraceoesophageal fistula Previous or current another malignant disease Any major surgery within the past 4 weeks.

**Exclusion criteria:**

**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**

Actual sample size reached: **69**

**Randomization (investigator's opinion)**

N/A

**Randomization description**

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethic Regional Committee Of Mashhad University Of Medical Sciences

**Street address**

Daneshgah Street, Goreishi Building

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9137744797

**Approval date**

2015-05-22, 1394/03/01

**Ethics committee reference number**

IR.MUMS.fm.REC.1394.64

**Health conditions studied**

1

**Description of health condition studied**

Esophageal Cancer

**ICD-10 code**

C15.1-C15.

**ICD-10 code description**

-Thoracic part of oesophagus-Abdominal part of oesophagus-Cardia

**Primary outcomes**

1

**Description**

Survival Rate

**Timepoint**

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

**Method of measurement**

Months that patient is without any sign or recurrent disease and survive after start of intervention.

**Secondary outcomes**

1

**Description**

1- Disease Free Survival (DFS) 2- Treatment toxicity

**Timepoint**

Every 3 months after start of intervention also following every cycle of chemotherapy.

**Method of measurement**

Months that patient survive after start of intervention.

**Intervention groups**

1

**Description**

Patients treat with the combination of cisplatin 30 mg

per square meter and irinotecan 65 mg per square meter in days 1 and 8 every 3 weeks at least 2 cycles during a course of 5-6 weeks radiotherapy of 5040 cGy and at most 3 cycles before surgery. Surgery is scheduled for 4-8 weeks after ending chemoradiation protocol.

#### Category

Treatment - Drugs

## 2

#### Description

Chemoradiation with paclitaxel-carboplatin regimen as a weekly schedule of paclitaxel 50 mg per square meter and carboplatin AUC=2 during 5-6 weeks radiotherapy of 5040 cGy. Surgery is scheduled for 4-8 weeks after ending chemoradiation protocol.

#### Category

Treatment - Drugs

## 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

##### Province

Razavi Khorasan

##### Postal code

9137913316

##### Phone

+98 51 3854 3031

##### Email

fazlm1@mums.ac.ir

### 2

#### Recruitment center

##### Name of recruitment center

Omid Hospital

##### Full name of responsible person

Mitra Fazl Ersi

##### Street address

Khohsangi street, Alandasht square, Omid hospital

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9176613775

##### Phone

+98 51 3846 1518

##### Email

fazlm1@mums.ac.ir

## 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

##### Province

Razavi Khorasan

##### Postal code

1025469852

##### Phone

+98 51 3841 2081

##### Email

ArdakanianM1@mums.ac.ir

#### 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

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

Cancer Research Center

##### Full name of responsible person

Mitra Fazl Ersi

##### Position

Specialist Doctor

##### Latest degree

Specialist

##### Other areas of specialty/work

Radiotherapy

##### Street address

Khohsangi street, Alandasht square, Omid hospital

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9176613775

**Phone**

+98 51 3846 1518

**Fax**

**Email**

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**

full Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Radiotherapy

**Street address**

Khoohsangy street, Alandasht square, Omid Hospital

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9176613775

**Phone**

+98 51 3846 1516

**Fax**

**Email**

Salekr@mums.ac.ir

**Web page address**

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Mitra Fazl Ersi

**Position**

Specialist

**Latest degree**

Specialist

**Other areas of specialty/work**

Radiotherapy

**Street address**

Mashhad, khohsangy streat, Alandasht Square, Omid Hospital

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9176613775

**Phone**

+98 51 3846 1518

**Fax**

**Email**

Fazlm1@mums.ac.ir

**Web page address**

## 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**

No - There is not 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**

Not applicable

**Data Dictionary**

Not applicable