

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 followed 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; tracheo-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

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9137913316

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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

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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

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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

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Khohsangi street, Alandasht square, Omid hospital

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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

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Contact

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Position

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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

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