Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of response and toxicity of capecitabine and oxaliplatin chemotherapy regimen with taxol and carboplatin with radiotherapy in esophageal cancer patients

Protocol summary

Study aim

Comparison of response and toxicity of two different regimens of chemotherapy with esophageal cancer

Design

The study is a clinical trial in which two groups of 35 patients are evaluated in parallel with two different chemotherapy regimens with radiotherapy and the patients rate of response (rate of pathologic response through surgery or re-endoscopy) as well as complications are compared. The study is a single-blind study and patients in each group are unaware of the treatment and outcome of the opposite group.

Settings and conduct

Patients were recruited in two groups of 35 patients with esophageal cancers diagnosed at Firoozgar Hospital and Haft Tir Hospital from 1396 to 1398. Patients in each group will receive a special chemotherapy regimen with radiotherapy and upon completion chemoradiotherapy, A group of patients who are candidates for surgery will undergo surgery, and a group of patients who are not candidates for surgery will undergo re-endoscopy (it is important to be diagnosed with EUS at the beginning of the disease diagnosis), and then patients will be compared in both groups for treatment response and complications with different chemotherapy regimens

Participants/Inclusion and exclusion criteria

Under 80 years of age. Do not have severe dysphagia. No cervical esophageal involvement.

Intervention groups

Two groups of 35 esophageal cancer patients receiving different chemotherapy regimens with radiotherapy will be compared. One group will receive taxol and carboplatin regimens with radiotherapy and one group will receive capecitabine and oxaliplatin with radiotherapy and will then compare the pathologic and clinical response rates and complications between the two groups.

Main outcome variables

Pathologic response rate. Clinical response rate. Complications include: diarrhea and fatigue. Anorexia rate. Neutropenia and thrombocytopenia. Esophagitis severity.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170306032913N4**
Registration date: **2020-02-16, 1398/11/27**
Registration timing: **registered_while_recruiting**

Last update: **2020-02-16, 1398/11/27**
Update count: **0**

Registration date

2020-02-16, 1398/11/27

Registrant information

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Alireza Nikoofar
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-03-21, 1396/01/01

Expected recruitment end date
2020-03-20, 1399/01/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of response and toxicity of capecitabine and oxaliplatin chemotherapy regimen with taxol and carboplatin with radiotherapy in esophageal cancer patients

Public title
Comparison of response and toxicity of capecitabine and oxaliplatin chemotherapy regimen with taxol and carboplatin with radiotherapy in esophageal cancer patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Proper Performance Status. No severe dysphagia
Exclusion criteria:
Age over 80. Cervical Esophageal involvement
Age
From **40 years** old to **80 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Patients are divided into two groups with two different chemotherapy regimens that are prescribed in combination with radiotherapy. The disadvantages are described in each group but patients in each group will not be aware of the other group's line therapy. It also analyzes data without any benefit or potential loss
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
Street address
Department of Radiotherapy,Firoozgar Hospital,Valadi Ave,Valiasr Square,Tehran
City
Tehran
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Postal code
1593748711
Approval date
2019-09-28, 1398/07/06
Ethics committee reference number
IR.IUMS.FMD.REC.1398.220

Health conditions studied

1

Description of health condition studied
Chemoradiotherapy in esophageal cancer patients
ICD-10 code
C15
ICD-10 code description
Malignant neoplasm of esophagus

Primary outcomes

1

Description
Pathologic and clinical response to chemoradiotherapy with two different regimens in esophageal cancer patients
Timepoint
Evaluation of response rate after completion of chemoradiotherapy and evaluation and comparison of complications during treatment
Method of measurement
Postoperative pathology report. EUS re-report after chemoradiotherapy

Secondary outcomes

empty

Intervention groups

1

Description
Control group of 35 esophageal cancer patients receiving weekly paclitaxel (75mg/m2) and carboplatin (AUC:2)regimen with 5 days a week radiotherapy (total dose:45-50Gy)

Category
Treatment - Drugs

2

Description
The intervention group of 35 esophageal cancer patients receiving capcitabine(625mg/m2 daily during radiotherapy) and weekly oxaliplatin (50 mg/m2) regimen with 5 days a week radiotherapy (total dose:45-50Gy)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Firoozgar hospital.
Full name of responsible person
Aida Cheraghi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Alireza Nikoofar
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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
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Alireza Nikoofar
Position
Associate Professor
Latest degree
Specialist
Other areas of specialty/work
Radiotherapy
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Person responsible for updating data

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Full name of responsible person

Aida Cheraghi

Position

resident

Latest degree

Specialist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All patient documentation, including participants' personal information, will be shared after unidentifiable individuals, and the main outcome will include the extent of pathologic and clinical response and the extent of any of the listed complications will be shared

When the data will become available and for how long

Access started in 1399

To whom data/document is available

The data will be available to researchers working in academic and scientific institutions

Under which criteria data/document could be used

The information will be made available to researchers who want to continue to plan or compare results with other regimens.

From where data/document is obtainable

Department of Radiotherapy, Firoozgar Hospital, Dr. Ali Reza Nikofar arnikoofar@gmail.com

What processes are involved for a request to access data/document

Visit to the Radiotherapy Department of Firoozgar Hospital and Dr. Nikoofar The applicant was provided with information for about a week

Comments