Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of efficacy and adverse effects of two chemotherapy regimens including carboplatin-paclitaxel and capecitabine-oxaliplatin in neo-adjuvant chemo-radiation of esophageal cancer for patients who were referred to Imam Khomeini cancer institute during year 95-96

Protocol summary

Study aim

Comparison of efficacy and adverse effects of two chemotherapy regimens including carboplatin-paclitaxel and capecitabine-oxaliplatin in neo-adjuvant chemo-radiation of esophageal cancer for patients who were referred to Imam Khomeini cancer institute during year 95-96

Design

Two arm parallel group randomised trial without blindness to assess the efficacy and adverse effects of chemotherapy regimens.

Settings and conduct

Trial will be conducted in Imam Khomeini cancer institute. Esophageal cancer patients who are candidate for neo-adjuvant chemo-radiation will be entered. This trail will be done without blinding.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Patients who are between 18-75 years old 2.Tumor should located in thoracic esophagus or gastro-esophageal junction. 3. Pathology consists of squamous cell carcinoma or adenocarcinoma. 4. Tumor should be resectable. 5. Disease should be curable Exclusion criteria: 1. Patient who suffers from bad performance status.

Intervention groups

Esophageal cancer patients will receive one of chemotherapy regimens as neo-adjuvant chemo-radiation. Intervention group will receive carboplatin-paclitaxel. Control group will get chemotherapy consist of capecibatine-oxaliplatin.

Main outcome variables

Tumor regression grade

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140903019036N3**
Registration date: **2018-08-17, 1397/05/26**
Registration timing: **registered_while_recruiting**

Last update: **2018-08-17, 1397/05/26**
Update count: **0**

Registration date

2018-08-17, 1397/05/26

Registrant information

Name
Borna Farazmand

Name of organization / entity
Tehran university of medical sciences

Country
Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-21, 1397/01/01

Expected recruitment end date

2019-03-21, 1398/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of efficacy and adverse effects of two chemotherapy regimens including carboplatin-paclitaxel and capecitabine-oxaliplatin in neo-adjuvant chemo-radiation of esophageal cancer for patients who were referred to Imam Khomeini cancer institute during year 95-96

Public title
Comparison of two chemotherapy regimens including carboplatin-paclitaxel and capecitabine-oxaliplatin in neo-adjuvant chemo-radiation of esophageal cancer
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Tumor should located in thoracic esophagus or gastro-esophageal junction. Patients' age should be between 18-75 years old. Pathology consists of squamous cell carcinoma or adenocarcinoma. Tumor should be resectable. Disease should be curable.
Exclusion criteria:
Patient who suffers from bad performance status.
Age
From **18 years** old to **75 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **92**
Randomization (investigator's opinion)
Randomized
Randomization description
Before starting the study, 4 part blocks consisting A and B were generated randomly. Patients were assigned to blocks consecutively. Codes were belonged to two groups consist of carboplatin-paclitaxel or capecitabine-oxaliplatin and so patients were randomized to two groups.
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
Ethics committee of Imam Khomeini Hospital
Street address
East Baqerkhan St, Chamran Highway, Tehran, Tehran Province
City
Tehran
Province
Tehran
Postal code
۱۴۱۹۷۳۳۱۴۱
Approval date
2017-09-04, 1396/06/13
Ethics committee reference number
IR.TUMS.IKHC.REC.1396.3365

Health conditions studied

1

Description of health condition studied
Esophageal cancer
ICD-10 code
C15.5
ICD-10 code description
Malignant neoplasm of lower third of esophagus

Primary outcomes

1

Description
Tumor regression grade
Timepoint
Tumor regression grade will determine once after surgery.
Method of measurement
Tumor regression grade will determine through surgical sample by pathologist.

Secondary outcomes

1

Description
Gastrointestinal adverse effects
Timepoint
Gastrointestinal adverse effects will be evaluated at 1 and 3 months after neo-adjuvant chemoradiation.
Method of measurement
Gastrointestinal adverse effects will be evaluated through CTCAE (Common Terminology Criteria for Adverse Events).

2

Description
Hematologic adverse effects
Timepoint
Hematologic adverse effects will be evaluated at 1 and 3 months after neo-adjuvant chemoradiation.
Method of measurement
Hematologic adverse effects will be evaluated through CTCAE (Common Terminology Criteria for Adverse

Events).

3

Description
Surgical margin's tumor remnant
Timepoint
Surgical margin's tumor remnant is determined once after surgery.
Method of measurement
Surgical margin's tumor remnant is determined through pathologist's assessment.

Intervention groups

1

Description
Intervention group: chemotherapy with oxaliplatin (85 mg/m2, week 1, 3, 5) + capecitabine (625mg/m2, BD, day 1 to 5, weekly), during radiotherapy
Category
Treatment - Drugs

2

Description
Control group: chemotherapy with carboplatin (AUC = 2) + Paclitaxel (50 mg/m2), weekly, during radiotherapy
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Iran cancer institute
Full name of responsible person
Borna Farazmand
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East Baqerkhan St, Chamran Highway, Tehran, Tehran Province
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr Ebrahim Esmati
Street address
East Baqerkhan St, Chamran Highway, Tehran, Tehran Province
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1419733141
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Email
eb_esmati@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences
Proportion provided by this source
40
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
Tehran University of Medical Sciences
Full name of responsible person
Borna Farazmand
Position
Resident of clinical oncology
Latest degree
Medical doctor
Other areas of specialty/work
Radiotherapy
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East Baqerkhan St, Chamran Highway, Tehran, Tehran Province
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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Ebrahim Esmati

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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Position
Resident of clinical oncology

Latest degree
Medical doctor

Other areas of specialty/work
Radiotherapy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Data of other research maybe becomes at risk

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
The report of study will be released

When the data will become available and for how long
It will be after publishing the paper.

To whom data/document is available
The results will be accessible for all

Under which criteria data/document could be used
To administer in clinical decision making the result will be accessible.

From where data/document is obtainable
To receive the results contact to correspondent.

What processes are involved for a request to access data/document
To receive the results contact to correspondent.

Comments