

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 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 trial will be done without blinding.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Patients who are between 18-75 years old 2. Tumor should be 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 capecitabine-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)

Phone

+98 21 8842 9230

Email address

borna1367@yahoo.com

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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b-farazmand@razi.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Ebrahim Esmati

Street address

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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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b-farazmand@razi.tums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Ebrahim Esmati

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

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Position

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Latest degree

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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