

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Determination of the pathological response of localized or locally advanced esophageal carcinoma to induction chemotherapy and concurrent chemotherapy with hypofractionated radiotherapy before surgery.

Protocol summary

Study aim

Determination of the pathological response of localized or locally advanced esophageal carcinoma to induction chemotherapy and concurrent chemotherapy with hypofractionated radiotherapy before surgery.

Design

An interventional trial, phase 2, without a control group, on 43 patients

Settings and conduct

Patients with esophageal cancer who have endoscopic biopsy confirming the diagnosis of SCC or adenocarcinoma and are referred to Omid, Imam Reza, and Hasheminejad hospitals in Mashhad are considered. Patients undergoing staging workup with barium swallowing x-ray and CT scan of the thorax and abdomen for local and distant lymphatic metastasis. Patients suspected of having a primary T1 or T4 tumor Will also be reviewed with endoscopic ultrasonography. Routine laboratory tests, including complete blood counts, liver and kidney function tests, and blood albumin levels are also requested.

Participants/Inclusion and exclusion criteria

Inclusion criteria: The presence of carcinoma in the thoracic or abdominal esophagus; Functional status greater or equal to 70% of the Karnofsky standard or equal or less than one of the ECOG standard; Presence of grade 3 and higher dysphagia or disease stage in T(2-4) N(0) M(0) or (any)T N(+) M(0) based on staging findings; Consent to complete the treatment program, including surgery. Exclusion criteria: Existence of metastatic disease; Presence of cervical esophageal carcinoma; Existence of invasion to heart, trachea, bronchus or aorta; Dissent to surgery; Existence of a previous history of cancer or other comorbidities that prevent the full implementation of the treatment program.

Intervention groups

Patients with esophageal carcinoma will undergo induction chemotherapy and then concurrent chemotherapy with hypofractionated radiotherapy, and after that tumor removal surgery will be performed for the patients.

Main outcome variables

Rate of pathological response

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210623051676N1**

Registration date: **2022-02-04, 1400/11/15**

Registration timing: **registered_while_recruiting**

Last update: **2022-02-04, 1400/11/15**

Update count: **0**

Registration date

2022-02-04, 1400/11/15

Registrant information

Name

Ali Emadi Torghabeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3842 6082

Email address

emadita@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-28, 1400/08/06

Expected recruitment end date

2024-01-26, 1402/11/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determination of the pathological response of localized or locally advanced esophageal carcinoma to induction chemotherapy and concurrent chemotherapy with hypofractionated radiotherapy before surgery.

Public title

hypofractionated radiotherapy in esophageal carcinoma

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

carcinoma in thoracic or abdominal esophagus
performance status above or equal to 70% in karnofsky
criteria or less or equal to 1 in ECOG criteria presence of
3rd grade or more dysphasia or disease in T2-T4 N0 M0
or any T N+ M0 stage consent to the whole treatment
program including surgery

Exclusion criteria:

presence of metastatic disease presence of cervical
esophagus invasion to heart, trachea, bronchus or aorta
dissent to surgery history of cancer or other diseases
that interfere to complete the treatment program

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 43

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**Ethics committee of Mashhad University of Medical
Sciences**Street address**

omid hospital, koohsangi Avn.

City

Mashhad

Province

Razavi Khorasan

Postal code

1377591766

Approval date

2021-10-27, 1400/08/05

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1400.482

Health conditions studied**1****Description of health condition studied**

esophageal cancer

ICD-10 code

C15.9

ICD-10 code description

Malignant neoplasm of esophagus, unspecified

Primary outcomes**1****Description**Percentage of pathological response based on tumor
necrosis in microscopic examination**Timepoint**4 weeks after completion of neoadjuvant
chemoradiotherapy**Method of measurement**

Pathological evaluation

Secondary outcomes**1****Description**

scale of dysphagia

Timepoint

before the intervention and after completing treatment

Method of measurement

dysphagia severity scale

Intervention groups**1****Description**

Intervention group: Received 3 to 5 courses of weekly induction chemotherapy with paclitaxel (50 mg / m²) and carboplatin (AUC 2) followed by hypofractionated radiotherapy with a total dose of 40 Gy and 2.5 Gy per fraction

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Omid hospital

Full name of responsible person

Shervin Mashregi Moghaddam

Street address

Omid hospital, Koohsangi Avn.

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9858795576

Phone

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Email

emp_shervin@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Majid Ghayour Mobarhan

Street address

Deputy of Research and Technology., Qoreshi building., Beside Hoveize cinema., Daneshgah Blvd

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vcresraech@mums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

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

Mashhad University of Medical Sciences

Full name of responsible person

Shervin Mashregi Moghaddam

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Radiotherapy

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Shervin Mashreghi Moghaddam

Position

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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 of data after making persons undetectable

When the data will become available and for how long

after publishing the outcomes

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

For research, treatment and educational purposes

From where data/document is obtainable

Refer to Shervin Mashreghi Moghaddam via email address or whatsapp number: emp_shervin@yahoo.com 00989358663171

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

Within a week

Comments