

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of addition of enoxaparin to neoadjuvant chemoradiation of esophageal cancer on the clinical and pathologic response and value of post-chemoradiation findings in prediction of complete pathologic response

#### Protocol summary

##### Summary

This is a randomized, single blind, multi center, phase two clinical trial. Inclusion criteria are consist of non-metastatic esophageal cancer who are going to receive chemo-radiotherapy. Sample size is 100 people (50 people in each group). In the intervention group, patients are going to inject an enoxaparin (40 mg) daily concurrent by chemo-radiation daily. Therefor patients with esophageal cancer are going to assign randomly to control group (only chemo-radiotherapy) and intervention group (chemo-radiotherapy+enoxaparin) using 1:1 allocation. Four to 6 weeks after treatment, all patients undergo upper GI endoscopy and then esophagectomy. Endoscopic and pathological findings (after esophagectomy) are considered as clinical and pathological response, respectively.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016070628814N1**

Registration date: **2016-07-17, 1395/04/27**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2016-07-17, 1395/04/27

##### Registrant information

##### Name

Arezou Gholami

##### Name of organization / entity

Department of Oncology, Omid Hospital, Mashhad

University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3802 2736

##### Email address

gholamia931@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, Mashhad University of Medical Sciences and Researcher

##### Expected recruitment start date

2016-07-22, 1395/05/01

##### Expected recruitment end date

2016-07-22, 1395/05/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of addition of enoxaparin to neoadjuvant chemoradiation of esophageal cancer on the clinical and pathologic response and value of post-chemoradiation findings in prediction of complete pathologic response

##### Public title

The effects of enoxaparin in treatment of esophageal cancer

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria are definitive diagnoses of esophageal cancer by oncologist and pathological evaluation, non-

metastatic esophageal cancer, patient who are candidate for chemo-radiation treatment, pathological report of SCC, normal CBC, normal kidney function test, normal liver function test, normal FBS. Exclusion criteria are previous history of chest wall radiotherapy, previous history of chemotherapy, past medical history of HTN, DM, renal failure and liver failure, pathological report of adenocarcinoma or small cell carcinoma, neoplasm of other organs, discontent for the study, inability to do daily radiotherapy, unwillingness to esophagectomy.

**Age**

No age limit

**Gender**

Both

**Phase**

2

**Groups that have been masked**

No information

**Sample size**

Target sample size: 100

**Randomization (investigator's opinion)**

Randomized

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

Single blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features**

Random allocation and blinding was done this way: using a computerized random number table, patients are going to assign to intervention or control groups. Patient are going to be blind about their interventions. Thus, this study is a randomized and single-blind.

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Medical ethics committee of Mashhad University of Medical Sciences

**Street address**

University St., Ghoraisly Building

**City**

Mashhad

**Postal code**

91375345

**Approval date**

2016-06-22, 1395/04/02

**Ethics committee reference number**

MUMS.fm.REC.1395.53

**2****Ethics committee****Name of ethics committee**

Added at 2016-07-22: Medical ethics committee of Mashhad University of Medical Sciences

**Street address**

Added at 2016-07-22: University St., Ghoraisly Building

**City**

Added at 2016-07-22: Mashhad

**Postal code**

Added at 2016-07-22:

**Approval date**

0623-12-31, 6/01/-1174

**Ethics committee reference number**

Added at 2016-07-22: MUMS.fm.REC.1395.80

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

Malignant neoplasm of oesophagus

**ICD-10 code**

C15

**ICD-10 code description**

Malignant neoplasm of oesophagus

**2****Description of health condition studied**

Follow-up examination after combined treatment for malignant neoplasm

**ICD-10 code**

Z08.7

**ICD-10 code description**

Follow-up examination after combined treatment for malignant neoplasm

**Primary outcomes****1****Description**

clinical response

**Timepoint**

4-6 weeks after complete of combined treatment

**Method of measurement**

according to endoscopic findings (no lesion, primary lesion or became smaller less than 50%of primary lesion, become smaller more than 50% of primary lesion)

**2****Description**

pathologic response

**Timepoint**

4-6weeks after complete of treatment

**Method of measurement**

according to pathologic findigs of esophagous specimen (complete Vs incompelet)

### 3

#### **Description**

R staging (residual of tumor)

#### **Timepoint**

intraoperative of esophagectomy

#### **Method of measurement**

according to surgeon findings when esophagectomy is done (gross residue, microscopic residue, without residue)

## **Secondary outcomes**

### 1

#### **Description**

heparin induced thrombocytopenia

#### **Timepoint**

before prescription of any course of chemotherapy

#### **Method of measurement**

according to CBC

## **Intervention groups**

### 1

#### **Description**

In the intervention group, patients are going to receive subcutaneous enoxaparin (40 mg) daily concurrent with chemo-radiotherapy.

#### **Category**

Treatment - Drugs

### 2

#### **Description**

chemo-radiotherapy.

#### **Category**

Treatment - Other

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Oncology clinic, Omid Hospital, Mashhad, Iran

##### **Full name of responsible person**

Dr. Taghizadeh Kermani, Ali

##### **Street address**

Department of Oncology, Omid Hospital, Mashhad  
University of Medical Sciences

##### **City**

Mashhad

### 2

#### **Recruitment center**

##### **Name of recruitment center**

Oncology clinic, Imam Reza Hospital, Mashhad, Iran

##### **Full name of responsible person**

Dr. Taghizadeh Kermani, Ali

#### **Street address**

Department of Oncology, Imam Reza Hospital,  
Mashhad University of Medical Sciences

#### **City**

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## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Vice chancellor for research, Mashhad University of  
Medical Sciences

##### **Full name of responsible person**

Tafaghodi, Mohsen

##### **Street address**

Ghoraishy Building, University St.

##### **City**

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#### **Grant name**

#### **Grant code / Reference number**

941703

#### **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**

*empty*

#### **Domestic or foreign origin**

*empty*

#### **Category of foreign source of funding**

*empty*

#### **Country of origin**

#### **Type of organization providing the funding**

*empty*

## **Person responsible for general inquiries**

#### **Contact**

##### **Name of organization / entity**

Radiation Oncology Department, Faculty of Medicine,  
Mashhad University of Medical Sciences

##### **Full name of responsible person**

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##### **Position**

Resident of Radiation Oncology

##### **Other areas of specialty/work**

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Web page address**

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*