

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Efficacy of intraoperative, single-bolus corticosteroid dose to prevent postoperative respiratory complication after transhiatal esophagectomy

Protocol summary

Summary

Study Goal: Pulmonary complications are the most common complications after esophageal resection. In this study we examined the effect of steroids administration during surgery to reduce postoperative morbidity with a focus on respiratory complications. include and exclude criteria: Patients who had appropriate indication for transhiatal esophagectomy were elected and dose who need neoadjuvant therapy or three hole esophagectomy excluded from study. studied population: Patients with esophageal cancer who underwent transhiatal esophagectomy, divided into two groups: The intervention group (received 125mg methylprednisolone sodium succinate) and a control group. number of cases: 60 patients studied interventions: Postoperative complications included anastomotic fistula, wound infection in the neck and abdomen and pulmonary complications. We analyzed pulmonary complications included pneumonia, ALI or ARDS occurred before the seventh day. The leukocyte count and CRP levels measured on the 2nd and 7th days after surgery. initial results: Preoperative single dose corticosteroids are effective in preventing pulmonary complications after transhiatal esophagectomy. Methylprednisolone reduced the increase in CRP levels after surgery and decreased blood leukocyte count more in postoperative period.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201710092517N3**

Registration date: **2017-10-28, 1396/08/06**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-10-28, 1396/08/06

Registrant information

Name

Reza Bagheri

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 921 346 3752

Email address

bagherir@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

none

Expected recruitment start date

2013-12-31, 1392/10/10

Expected recruitment end date

2015-12-31, 1394/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of intraoperative, single-bolus corticosteroid dose to prevent postoperative respiratory complication after transhiatal esophagectomy

Public title

Efficacy of intraoperative, corticosteroid to prevent postoperative respiratory complicationl esophagectomy

Purpose

Prevention

Inclusion/Exclusion criteria

inclusion criteria: esophageal cancer; indication for transhiatal esophagectomy; not using corticosteroids; tending to participate in the study exclusion criteria: change in surgery program; use of cortons before surgery; need neoadjuvant therapy; three hole esophagectomy

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description**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**

mashhad univcrity of medical sciences

Street address

daneshgah st.

City

Mashhad

Postal code

098

Approval date

2014-07-26, 1393/05/04

Ethics committee reference number

IR.mums.REC.1393.137

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

esophageal cancer

ICD-10 code

C15.9

ICD-10 code description

Malignant neoplasm of oesophagus

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

respiratory complications

Timepoint

2nd and 7th days after surgery

Method of measurement

blood factors (cc)

Secondary outcomes

empty

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

the control group did not received the corton

Category

Treatment - Drugs

2**Description**

The intervention group received 125mg methylprednisolone sodium succinate

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Qaem Hosp.

Full name of responsible person

Reza Bagheri

Street address

Ahmadabad street, Qaem hospital

City

Mashhad

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Reza Bagheri

Street address

Qaem Hospital

City

Mashhad

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

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**

mashhad university of medical sciences

Full name of responsible person

dr. Reza Bagheri

Position

MD

Other areas of specialty/work**Street address**

Qaem hospital

City

Mashhad

Postal code

098

Phone

+98 921 346 3752

Fax**Email**

bagherir@mums.ac.ir

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

mashhad university of medical sciences

Full name of responsible person

Dr. Reza Bagheri

Position

MD

Other areas of specialty/work**Street address**

qaem Hsp.

City

Mashhad

Postal code

098

Phone

+98 921 346 3752

Fax**Email**

bagherir@mums.ac.ir

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Ebne sina st. Emam Reza hospital

Full name of responsible person

Reza Bagheri

Position**Other areas of specialty/work****Street address**

Ebne sina st. Emam Reza hospital

City

Mashhad

Postal code

098

Phone

+98 921 346 3752

Fax**Email**

bagherir@mums.ac.ir

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