

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

### Evaluation the effect of mechanical ventilation with a tidal volume of 10 ml / kg and 6 ml / kg during abdominal cancer surgery on the rate of compliance and airway resistance of patients

#### Protocol summary

##### Study aim

The aim of this study was to evaluate the rate of airway compliance and resistance in abdominal cancer surgery and compare two groups receiving high current volume of 10 mL / kg and low current volume of 6 mL / kg.

##### Design

Interventional study with a control group of parallel, randomized, double-blind Phase 3 using the table of random numbers that were performed on 80 patients

##### Settings and conduct

This study was performed on 90 patients with upper and lower gastrointestinal cancers referred to Imam Reza Hospital in Mashhad, who were randomly divided into intervention and control groups. The first group of patients underwent ventilation with a volume of 10 ml / kg and the number of breaths is 8 (peep = 5), and the second is mechanically ventilated with a volume of 6 mL / kg and a number of breaths of 14. The effect of this intervention is evaluated before and 2 hours after the operation using the mentioned criteria.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria included patients aged 20-65 years who are candidates for elective abdominal surgery due to cancer and non-admission conditions for diseases such as chronic lung diseases like asthma and heart

##### Intervention groups

In control group, after anesthesia in abdominal cancer surgery .Mechanical ventilation is performed with positive end-expiratory pressure (number of breaths 14 with Peep = 5) and low volume at 6 ml / kg and intervention group Mechanical ventilation is performed with positive end-expiratory pressure (number of breaths 8 with Peep = 5) and high volume at 10 ml / kg

##### Main outcome variables

Compliance and airway resistance in abdominal cancer surgery

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20101130005280N35**

Registration date: **2020-12-28, 1399/10/08**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-12-28, 1399/10/08**

Update count: **0**

##### Registration date

2020-12-28, 1399/10/08

##### Registrant information

##### Name

Raheleh Nejati

##### Name of organization / entity

Mashhad University of Medical Scinces, Ibn-e- Sina  
Psychiatric Hospital

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3711 2540

##### Email address

nejatir2@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-11-21, 1399/09/01

##### Expected recruitment end date

2021-02-19, 1399/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

## Trial completion date

empty

## Scientific title

Evaluation the effect of mechanical ventilation with a tidal volume of 10 ml / kg and 6 ml / kg during abdominal cancer surgery on the rate of compliance and airway resistance of patients

## Public title

The effect of mechanical ventilation during abdominal cancer surgery in improving pulmonary complications

## Purpose

Supportive

## Inclusion/Exclusion criteria

### Inclusion criteria:

Candidate for elective abdominal surgery due to cancer

People in the age range of 65-65 years

### Exclusion criteria:

Other diseases such as chronic lung disease like asthma and COPD and heart disease or kidney failure Existence of other concomitant surgeries such as thoracic surgery

History of previous lung surgery

## Age

From **20 years** old to **65 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant
- Outcome assessor

## Sample size

Target sample size: **90**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Simple randomization with table of random numbers available at "www.randomization.com" website will be used. Numbers will be placed in sealed envelopes and each envelope is assigned to one participant placing them in one of the two groups.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

In this study, participants are not aware of the intervention. Also, outcome assessors are unaware of how patients are grouped, although patients are aware of the project after receiving full explanations and even an invitation from the patients' families, but they do not know which group they are in.

## Placebo

Not used

## Assignment

Parallel

## 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

Daneshgah street, Ghoreishi building

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

91778-99191

#### Approval date

2020-05-27, 1399/03/07

#### Ethics committee reference number

IR.MUMS.MEDICAL.REC.1399.519

## Health conditions studied

### 1

#### Description of health condition studied

abdomen cancer

#### ICD-10 code

D21.4

#### ICD-10 code description

Benign neoplasm of connective and other soft tissue of abdomen

## Primary outcomes

### 1

#### Description

Compliance rate

#### Timepoint

At the beginning of the study (before the intervention) and 2 hours after the surgery

#### Method of measurement

Ventilator

### 2

#### Description

Airway resistance

#### Timepoint

At the beginning of the study (before the intervention) and 2 hours after the surgery

#### Method of measurement

Ventilator

## Secondary outcomes

empty

## Intervention groups

## 1

### Description

Intervention group: In the intervention group, after anesthesia in abdominal cancer surgery and manual ventilation with a mask 8-10 times per minute and passed 2 minutes when the patient's jaw is relaxed the patient is intubated and after confirmation of the patient's tube Correct location, ventilation or auxiliary mechanical ventilation for the patient is done. Mechanical ventilation is performed with a positive end-expiratory pressure (8 breaths = 5 peeps) and a high current volume of 10 ml / kg. Mechanical ventilation is an essential support method for maintaining adequate gas exchange during general anesthesia, which prevents postoperative complications, hypoxemia, and improves lung function.

### Category

Prevention

## 2

### Description

Control group: In this group, after anesthesia in abdominal cancer surgery and manual ventilation with a mask 8-10 times per minute and after 2 minutes when the patient's jaw is relaxed, the patient is intubated and after confirmation of the patient's tube Correct location ventilation or auxiliary mechanical ventilation for the patient is done. Mechanical ventilation is performed with positive end-expiratory pressure (number of breaths 14 with Peep = 5) and low volume at 6 ml / kg

### Category

Prevention

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Imam Reza Hospital

#### Full name of responsible person

Rahele Nejati

#### Street address

Ebne Sina St. Imam Reza Hospital

#### City

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#### Province

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#### Postal code

9137913316

#### Phone

+98 51 3854 3031

#### Email

Nejatir2@mums.ac.ir

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Mashhad University of Medical Sciences

#### Full name of responsible person

Dr.Mohsen Tafaghodi

#### Street address

Central Building of Mashhad University of Medical Sciences (Ghoreishi), Daneshgah 16, Daneshgah street

#### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

9177899191

#### Phone

+98 51 3841 2081

#### Email

ramresearch@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

Majid Razavi

#### Position

Associate professor

#### Latest degree

Subspecialist

#### Other areas of specialty/work

Anesthesiology

#### Street address

Ebne Sina St., Imam Reza Hospital

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## Person responsible for scientific inquiries

### Contact

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**Position**

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## Person responsible for updating data

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Associate professor

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## Sharing plan

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

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available