

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 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)

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+98 51 3711 2540

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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

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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

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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

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Person responsible for scientific inquiries

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Full name of responsible person

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Latest degree

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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

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Majid Razavi

Position

Associate professor

Latest degree

Subspecialist