Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparative study of Rocuronium deep muscular blockage in Isofluorane and Total Intravenous Anesthesia (TIVA) on peritoneal compliance and surgical conditions during laparoscopic cholecystectomy

Protocol summary

Study aim
Comparative study of Rocuronium deep muscular blockage in two anesthesia groups on peritoneal compliance and surgical conditions in laparoscopic cholecystectomy

Design
80 patients who are candidates for laparoscopic cholecystectomy are classified in two groups. The first group receives inhalation anesthesia and the maintance with Isofluoran, Remifentanil, and mixture of air and oxygen. The second group receives total intravenous anesthesia with Propofol and Remifentanil and a mixture of oxygen and air. The muscular relaxant used in both groups is Rocronium. The extent of relaxation will be monitored. Deep muscular blockage is called TOF = 0 and PTC = 0-4. Peritoneal pressure and the quality of operating conditions will be studied using conventional methods and compared in two groups.

Settings and conduct
Muscular blockage is monitored to maintain TOF = 1-3 and PTC = 4-8, and the Rocuronium infusion is started at a rate of 20 mg per hour and titrated for relaxation. To achieve TOF = 0 and PTC = 0-4, the surgeon's satisfaction and the quality of the operating conditions are recorded. This study will be conducted in Imam Reza Hospital of Tabriz University of Medical Sciences.

Participants/Inclusion and exclusion criteria
Patients with cholecystitis undergoing laparoscopic cholecystectomy Age of 18-65 years BMI < 35 Conscious consent Lack of allergic reactions to all medications used Lack of hypertension, liver, kidney, lung and neuromuscular diseases, no history of aspiration, active infection, dwarf

Intervention groups
Group one: Deep muscular blockage of Rocoronium in patients with inhalation anesthesia Group two: Deep muscular blockage of Rocoronium in patients with total intravenous anesthesia

Main outcome variables
Intra-abdominal pressure and quality of surgical conditions

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220519054914N1**
Registration date: **2022-07-01, 1401/04/10**
Registration timing: **prospective**

Last update: **2022-07-01, 1401/04/10**
Update count: **0**

Registration date
2022-07-01, 1401/04/10

Registrant information

Name
Hamzeh Hosseinzadeh

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-09-23, 1401/07/01

Expected recruitment end date
2023-09-23, 1402/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of Rocuronium deep muscular blockage in Isofluorane and Total Intravenous Anesthesia (TIVA) on peritoneal compliance and surgical conditions during laparoscopic cholecystectomy

Public title

Comparative study of Rocuronium deep muscular blockage in laparoscopic cholecystectomy

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Patients undergoing laparoscopic cholecystectomy Conscious consent for study No allergic reaction to all drugs used BMI (Body Mass Index) <35 Lack of hypertension, respiratory disease, history of aspiration, liver and kidney diseases, neuromuscular diseases, dwarf and patients with active infection

Exclusion criteria:

Dissatisfaction BMI>35 Patients whose operation is finally opened Allergic reaction to all drugs used Hypertension, respiratory disease, history of aspiration, liver and kidney diseases, neuromuscular diseases, dwarf and patients with active infection

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

After the initial diagnosis, patients are divided into groups of one or two based on a sealed envelope to be nominated for surgery. Group one will receive the inhalation method and the second group will receive the complete intravenous method. It should be noted that it is typed in approximately 40 envelopes of group one and in the next 40 envelopes of the second group, and each patient chooses an envelope without knowing the contents of the envelope.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The patient, the surgeon, and the person who is collecting the data are blinded to the type of anesthesia and the details.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

No. 21, Nastaran 4, Babaei 1 Ave., Parvaz Alley, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5167754836

Approval date

2022-04-22, 1401/02/02

Ethics committee reference number

IR.TBZMED.REC.1401.141

Health conditions studied

1

Description of health condition studied

Deep muscular blockage with Rocoronium and abdominal compliance

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The effect of deep muscular blockage on intra-abdominal pressure in laparoscopic cholecystectomy after inhaled anesthesia in laparascopic cholecystectomy

Timepoint

Muscular blockage is monitored to maintain TOF = 1-3, PTC = 4-8. To maintain the blockage, Rocuronium infusion is started at a rate of 20 mg per hour and titrated for the desired relaxation. Intra-abdominal pressure is measured at this rate of relaxation. In groups with deep relaxation, the rate of Rocronium infusion will be increased and titrated to achieve TOF = 0 and PTC = 0-4. Changes in abdominal pressure are measured in both anesthesic methods.

Method of measurement

Intra-abdominal pressure will be measured with

laparoscope and the abdominal compliance by measuring the length of the xiphoid to the pubis

2

Description
The effect of deep muscular blockage with Recuronium on intra-abdominal pressure in laparoscopic cholecystectomy with total intravenous anesthesia
Timepoint
Before and after deep muscular blockage
Method of measurement
The TOF and POC values will be measured before and after deep muscular blockage

Secondary outcomes

1

Description
The effect of deep muscular blockage with Recuronium on the quality of operating conditions in laparoscopic cholecystectomy anesthesized with isoflurane
Timepoint
Before and after deep muscular blockage
Method of measurement
1: Extremely poor conditions: the surgeon is unable to work because of coughing or because of the inability to obtain a visible laparoscopic field because of inadequate muscle relaxation. Additional neuromuscular blocking agents must be given.2: Poor conditions: there is a visible laparoscopic field, but the surgeon is severely hampered by inadequate muscle relaxation with continuous muscle contractions, movements, or both with the hazard of tissue damage. Additional neuromuscular blocking agents must be given.3: Acceptable conditions: there is a wide visible laparoscopic field, but muscle contractions, movements, or both occur regularly, causing some interference with the surgeon’s work. There is a need for additional neuromuscular blocking agents to prevent deterioration.4: Good conditions: there is a wide laparoscopic working field with sporadic muscle contractions, movements, or both. There is no immediate need for additional neuromuscular blocking agents unless there is a fear of deterioration.5: Optimal conditions: there is a wide visible laparoscopic working field without any movement or contractions.

2

Description
The effect of deep muscular blockage with Rocronium on the quality of operating conditions in laparoscopic cholecystectomy with total intra venous anesthesia
Timepoint
Before and after deep muscular blockage
Method of measurement
1: Extremely poor conditions: the surgeon is unable to work because of coughing or because of the inability to obtain a visible laparoscopic field because of inadequate muscle relaxation. Additional neuromuscular blocking agents must be given.2: Poor conditions: there is a visible laparoscopic field, but the surgeon is severely hampered by inadequate muscle relaxation with continuous muscle contractions, movements, or both with the hazard of tissue damage. Additional neuromuscular blocking agents must be given.3: Acceptable conditions: there is a wide visible laparoscopic field, but muscle contractions, movements, or both occur regularly, causing some interference with the surgeon’s work. There is a need for additional neuromuscular blocking agents to prevent deterioration.4: Good conditions: there is a wide laparoscopic working field with sporadic muscle contractions, movements, or both. There is no immediate need for additional neuromuscular blocking agents unless there is a fear of deterioration.5: Optimal conditions: there is a wide visible laparoscopic working field without any movement or contractions.

Intervention groups

1

Description
The first intervention group: Deep muscular blockage (TOF=0 or PTC=0-4) with Rocuronium accompanied by inhalation anesthesia
Category
Treatment - Surgery

2

Description
The second intervention group: Deep muscular blockage (TOF=0 or PTC=0-4) with Rocuronium accompanied by total intravenous anesthesia
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Hamzeh Hosseinzadeh
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
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Full name of responsible person
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Position
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Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no more information.

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
No - There is not 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