

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### Comparison of Tramadol and Lidocaine and placebo jelly in 150 patients candidate for laparoscopic cholecystectomy from bucking, coughing and sore throat after endotracheal extubation.

#### Protocol summary

##### Summary

This study will be done with aim to compare the effects of lidocaine topical gel with tramadol gel on coughing, straining and throat caused by the endotracheal tube. Inclusion criteria are: age between 20 and 60 years; patient informed consent; patients admitted for cholecystectomy laparoscopic surgery; ASA class 1,2; mallampati 1 or 2 and Exclusion criteria are: history of smoking or drug abuse; a history of catching a cold in the last two weeks; patients with COPD, and convulsions. This is a double blind experimental study. The study population consisted of patients undergoing laparoscopic cholecystectomy that referring to Imam Reza Hospital of Kermanshah and by random permutation blocks 150 persons will selected and will divided in five equal groups. All patients in the same way with propofol 2 mg / kg and midazolam 0.01 mg / kg and sufentanil 0.2 mg / kg and neuromuscular 0,5 mg / kg will put under general anesthesia. Isoflurane gas is used to maintain anesthesia. In the first group endotracheal tube cuff with tramadol gel 2.5%, in the second group with tramadol gel 5%, the third group with lidocaine gel 2% and in the fourth group is smeared with 1cc Of each of pure gel. In the control group do not use the gel and intubation performed as usual. The patients for the occurrence of straining and cough and laryngospasm and bronchospasm will control and data will recorded in a special form. Then all patients at a distance of one, six and twelve hours after the operation will checked in severity of throat pain using the VAS and information will recorded.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201507114938N3**

Registration date: **2016-02-12, 1394/11/23**

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

Last update:

Update count: **0**

##### Registration date

2016-02-12, 1394/11/23

##### Registrant information

###### Name

HOSSEIN FARZAM

###### Name of organization / entity

KERMANSHAH UNIVERSITY OF MEDICAL SCIENCES

###### Country

Iran (Islamic Republic of)

###### Phone

+98 83 1835 4434

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##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

##### Expected recruitment start date

2015-03-20, 1393/12/29

##### Expected recruitment end date

2016-03-19, 1394/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of Tramadol and Lidocaine and placebo jelly

in 150 patients candidate for laparoscopic cholecystectomy from bucking, coughing and sore throat after endotracheal extubation.

KUMS.REC.1394.16

### Public title

A comparative study of Tramadol and Lidocaine jelly effect on coughing , straining and sore throat due to tracheal tube

### Purpose

Treatment

### Inclusion/Exclusion criteria

Inclusion criteria: age between 20 and 60 years; patient informed consent; patients admitted for cholecystectomy laparoscopic surgery; ASA class 1,2; mallampati 1 or 2; TMD >6cm. Exclusion criteria: history of smoking or drug abuse; a history of catching a cold in the last two weeks; patients with COPD, asthma and convulsions.

### Age

From **20 years** old to **60 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **150**

### Randomization (investigator's opinion)

Randomized

### Randomization description

### Blinding (investigator's opinion)

Double blinded

### Blinding description

### Placebo

Used

### Assignment

Parallel

### Other design features

Randomly by permutation of blocks

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Committee Ethics, Kermanshah University of Medical Sciences

##### Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

##### City

kermanshah

##### Postal code

#### Approval date

2015-10-24, 1394/08/02

#### Ethics committee reference number

## Health conditions studied

### 1

#### Description of health condition studied

medical surveillance following treatment

#### ICD-10 code

Z09.0

#### ICD-10 code description

Follow-up examination after surgery for other conditions

## Primary outcomes

### 1

#### Description

sore throat

#### Timepoint

1 and 6 and 12 hours after extubation

#### Method of measurement

VAS

### 2

#### Description

coughing

#### Timepoint

Immediately after extubation

#### Method of measurement

By asking of patient

### 3

#### Description

straining

#### Timepoint

extubation time

#### Method of measurement

By asking of patient

## Secondary outcomes

### 1

#### Description

laryngospasm

#### Timepoint

after extubation

#### Method of measurement

exist - lack

### 2

#### Description

bronchospasm

#### Timepoint

after extubation

#### Method of measurement

exist - lack

## Intervention groups

### 1

#### Description

In the first group patients in the same way with propofol 2 mg / kg and midazolam 0.01 mg / kg and sufentanil 0.2 mg / kg and neuromuscular 0,5 mg / kg will put under general anesthesia. Isoflurane gas is used to maintain anesthesia. Then endotracheal tube cuff with tramadol gel 2.5%, is smeared. Then all patients at a distance of one, six and twelve hours after the operation will checked in severity of throat pain using the VAS, and information will recorded.

#### Category

Treatment - Drugs

### 2

#### Description

In the second group patients in the same way with propofol 2 mg / kg and midazolam 0.01 mg / kg and sufentanil 0.2 mg / kg and neuromuscular 0,5 mg / kg will put under general anesthesia. Isoflurane gas is used to maintain anesthesia. Then endotracheal tube cuff with tramadol gel 5%, is smeared. Then all patients at a distance of one, six and twelve hours after the operation will checked in severity of throat pain using the VAS, and information will recorded.

#### Category

Treatment - Drugs

### 3

#### Description

In the third group patients in the same way with propofol 2 mg / kg and midazolam 0.01 mg / kg and sufentanil 0.2 mg / kg and neuromuscular 0,5 mg / kg will put under general anesthesia. Isoflurane gas is used to maintain anesthesia. Then endotracheal tube cuff with tramadol gel 2%, is smeared. Then all patients at a distance of one, six and twelve hours after the operation will checked in severity of throat pain using the VAS, and information will recorded.

#### Category

Treatment - Drugs

### 4

#### Description

In the fourth group patients in the same way with propofol 2 mg / kg and midazolam 0.01 mg / kg and sufentanil 0.2 mg / kg and neuromuscular 0,5 mg / kg will put under general anesthesia. Isoflurane gas is used to maintain anesthesia. Then endotracheal tube cuff with tramadol gel 5%, is smeared. Then all patients at a distance of one, six and twelve hours after the operation will checked in severity of throat pain using the VAS, and information will recorded.

#### Category

Treatment - Drugs

### 5

#### Description

In the control group do not use the gel and intubation performed as usual. The patients for the occurrence of straining and cough and laryngospasm and bronchospasm will control by a person who is unaware of the type of gel used and data will recorded in a special form. Then all patients at a distance of one, six and twelve hours after the operation will checked in severity of throat pain using the VAS, and information will recorded

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Emam Reza Hospital

##### Full name of responsible person

Maryam Rahmatinejad

##### Street address

Emam Reza Hospital, Parastar Boulevard

##### City

Kermanshah

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research, Kermanshah University of Medical Sciences

##### Full name of responsible person

Koroush Hamzehee

##### Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

##### City

Kermanshah

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Vice chancellor for research, Kermanshah 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**

kermanshah univrsty of medical science

**Full name of responsible person**

Maryam Rahmatinejad

**Position**

Resident of Anesthesiolog

**Other areas of specialty/work**

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## Person responsible for updating data

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## Person responsible for scientific inquiries

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## 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*