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 blocks150 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 0f 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

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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.

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
kUMS.REC.1394.16

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 hourse after extubation
Method of measurement
VAS

2

Description
coughing
Timepoint
Immediately aftr 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 forth 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

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Person responsible for updating data

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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