Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Sep 2026

Comparison of nebulizer Method with intratracheal lidocaine injection to reduce pain and cough reflex during bronchoscopy.

Protocol summary

Study aim
Comparison of nebulizer Method with intratracheal lidocaine injection to reduce pain and cough reflex during bronchoscopy.

Design
Clinical trial with intervention and control groups, 96 patients were randomized with blocking and parallel and non blinded.

Settings and conduct
This study is done in the bronchoscopy unit of the Sabzevar Vasei Hospital. The subjects are anesthetized in one of two ways and then undergo bronchoscopy. The number of coughs is included in the process and at the end of the pain patients are measured at a numerical scale.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: 1.Being awake and conscious 2.The ability to collaborate 3.Informed consent 4.Literacy to reading and writing 5.Physical and mental health 6.Ages of 18 to 68 years old Exclusion criteria: 1.Patients with GCS less than 13 2.Patients with seizure disorders 3.Patients with coagulation abnormalities 4.Patients with a history of lidocaine allergy 5.Patients with history of respiratory tract surgery 6.patients with history of diabetes more than 10 years 7.Drug addiction 8.Previous Bronchoscopy history

Intervention groups
Control group: Patients in this group undergo local anesthesia through the work channel of scope via squirting 10-cc (Split up) lidocaine(lignocaine) ampoule of two percent of the product of the Rasht Pharmaco Company on the vocal cords and lower respiratory tract and then bronchoscopy is done. Intervention group: : patients in this group, undergo local anaesthesia of respiratory tract by inhaling 10cc of Lidocaine (2%), product of Rasht Farmacoy company, through a nebulizer and then bronchoscopy is done.

Main outcome variables
pain ; cough

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181004041230N1**
Registration date: **2018-10-30, 1397/08/08**
Registration timing: **registered_while_recruiting**

Last update: **2018-10-30, 1397/08/08**
Update count: **0**

Registration date
2018-10-30, 1397/08/08

Registrant information

Name
Saeed Islamitabar

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 4441 7559

Email address
saeedislamitabar@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-10-23, 1397/08/01

Expected recruitment end date
2019-02-20, 1397/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparison of nebulizer Method with intratracheal lidocaine injection to reduce pain and cough reflex during bronchoscopy.

Public title
Comparison of two different local anesthetics, during bronchoscopy.
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Being awake and conscious The ability to collaborate Informed consent Literacy to reading and writing Physical and mental health Ages of 18 to 68 years old
Exclusion criteria:
Patients with GCS less than 13 Patients with seizure disorders Patients with coagulation abnormalities Patients with a history of lidocaine allergy Patients with history of respiratory tract surgery patients with history of diabetes more than 10 years Drug addiction Previous bronchoscopy history
Age
From **18 years** old to **68 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **96**
Randomization (investigator's opinion)
Randomized
Randomization description
Samples will be selected in convenient Sampling method and for restricted randomization, the type of permuted blocks,by using R software, sextet blocks are created and sample people are placed in the intervention or control group.concealment are done with sequentially numbered, sealed, opaque envelopes and kept by the Statistics Consultant.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Sabzevar University of Medical Sciences
Street address
Campus University.,Tohid Shahr Blvd
City
Sabzevar
Province
Razavi Khorasan
Postal code
9617213112
Approval date
2018-09-29, 1397/07/07
Ethics committee reference number
IR.MEDSAB.REC.1397.038

Health conditions studied

1

Description of health condition studied
Respiratory disorder, unspecified
ICD-10 code
J98.9
ICD-10 code description
Respiratory disorder, unspecified

Primary outcomes

1

Description
Pain
Timepoint
At the end of bronchoscopy
Method of measurement
Numerical pain rating scale

2

Description
Cough
Timepoint
During the procedure
Method of measurement
Counting coughs by an assessor

Secondary outcomes

empty

Intervention groups

1

Description
Control group: Patients in this group undergo local anesthesia through the work channel of scope via squirting 10-cc (Split up) lidocaine(lignocaine) ampoule of two percent of the product of the Rasht Pharmaco Company on the vocal cords and lower respiratory tract and then bronchoscopy is done.
Category
Prevention

2

Description
Intervention group: : patients in this group, undergo local anaesthesia of respiratory tract by inhaling 10cc of Lidocaine (2%), product of Rasht Farmacoy company, through a nebulizer and then bronchoscopy is done.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Vasei hospital
Full name of responsible person
Saeed Islamitabar
Street address
Tohid shahr Blvd.,Vasei hospital
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9613873136
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vasei.h@medsab.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sabzevar University of Medical Sciences
Full name of responsible person
Tadayonfar Mosareza
Street address
University campus.,Tohid shahr Blvd
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Email
mtadayonfar@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Sabzevar 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
Sabzevar University of Medical Sciences
Full name of responsible person
Saeed Islamitabar
Position
Masters student of intensive care
Latest degree
Bachelor
Other areas of specialty/work
Nursery
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Position
Master`s Degree
Latest degree
Master
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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
Saeed Islamitabar

Position
Masters student of intensive care

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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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