

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 Pharmacology 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 Farmaco 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.		Street address Campus University.,Tohid Shahr Blvd	
Public title Comparison of two different local anesthetics, during bronchoscopy.		City Sabzevar	
Purpose Prevention		Province Razavi Khorasan	
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		Postal code 9617213112	
Age From 18 years old to 68 years old		Approval date 2018-09-29, 1397/07/07	
Gender Both		Ethics committee reference number IR.MEDSAB.REC.1397.038	
Phase 3		Health conditions studied 1 Description of health condition studied Respiratory disorder, unspecified ICD-10 code J98.9 ICD-10 code description Respiratory disorder, unspecified	
Groups that have been masked <i>No information</i>		Primary outcomes 1 Description Pain Timepoint At the end of bronchoscopy Method of measurement Numerical pain rating scale	
Sample size Target sample size: 96		2 Description Cough Timepoint During the procedure Method of measurement Counting coughs by an assessor	
Randomization (investigator's opinion) Randomized		Secondary outcomes empty	
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.		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	
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			

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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

City

Sabzevar

Province

Razavi Khorasan

Postal code

9613873136

Phone

+98 51 4465 1300

Email

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

City

sabzevar

Province

Razavi Khorasan

Postal code

9613873136

Phone

+98 51 4401 1300

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

Street address

university campus.,Tohid shahr Blvd

City

Sabzevar

Province

Razavi Khorasan

Postal code

9613873136

Phone

+98 51 4401 1300

Email

saeedislamitabar@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Mosareza Tadayonfar

Position

Master`s Degree

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

University Campus.,Tohid Shahr Blvd

City

Sabzevar

Province

Razavi Khorasan

Postal code

9613873136

Phone

+98 51 4401 1300

Email

mtadayonfar@yahoo.com

Person responsible for updating data

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

Street address

university campus.,Tohid Shahr Blvd

City

Sabzevar

Province

Razavi Khorasan

Postal code

9613873136

Phone

+98 51 4401 1300

Email

saeedislamitabar@yahoo.com

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