Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of patient satisfaction during flexible bronchoscopy by local anesthesia done with lidocaine spraying or conjunctive use of airway neural block and lidocaine spraying

Protocol summary

Study aim
Comparison of patient satisfaction during flexible bronchoscopy by local anesthesia done with lidocaine spraying or conjunctive use of airway neural block and lidocaine spraying

Design
Randomized clinical trial , two arm blinded, with a parallel group design will perform and the sample size will be 60 patients

Settings and conduct
Study will perform in Imam Khomeini Hospital of Tehran, patients will divide into two groups. In the first group, local anesthetic will be "spray as you go". In the second group, in addition to the "spray as you go" method, airway nerve block is also done. Sedation and nerve block will perform by anesthesiologist. The injection site for nerve block is covered in all patients with three small adhesives, thus, the bronchoscopist is not known from the patient group. Patient satisfaction will be measured in the recovery room by the unaware nurse to the patient's group and after the patient's complete consciousness.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Clinical Indication for Diagnostic Bronchoscopy At least 18 years old Stable hemodynamic status in the patient Exclusion criteria: Pregnancy Coagulation disorders

Intervention groups
In the first group, local anesthetia will be "spray as you go". In the second group, in addition to the "spray as you go" method, Airway Nerve Block will also done.

Main outcome variables
Patient satisfaction during flexible bronchoscopy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130210012419N3**
Registration date: **2018-12-14, 1397/09/23**
Registration timing: **prospective**

Last update: **2018-12-14, 1397/09/23**
Update count: **0**

Registration date
2018-12-14, 1397/09/23

Registrant information

Name
Mehrnaz Asadi Gharabaghi

Name of organization / entity
Tehran University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-12-21, 1397/09/30

Expected recruitment end date
2019-01-20, 1397/10/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparison of patient satisfaction during flexible bronchoscopy by local anesthesia done with lidocaine spraying or conjunctive use of airway neural block and lidocaine spraying

Public title
Effect of airway neural block on patient satisfaction during bronchoscopy
Purpose
Diagnostic
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnostic Bronchoscopy is clinically indicated Patients will be older than 18 years old Stable hemodynamic status
Exclusion criteria:
Patient’s dissatisfaction Pregnancy Coagulation disorder and using anticoagulant drugs
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization will perform with randomized block design and using of random number table. Sixty patients will place in 15 blocks. Within each block will be 4 patients, then the numbering of blocks will do using a random number table, in each block two patients belong to the intervention group and two other patients belong to the control group. The layout of the block's people in the two groups (intervention or control group) will be randomized with a random number table. Determination of all possible blocks will be based on the layout of individuals next to each other inside block and the block's number. The entry of individuals to each of the groups will be respectively the block's number choices and the layout in the block.
Blinding (investigator's opinion)
Double blinded
Blinding description
The injection site for the nerve block will cover in all patients in group one and two with three small adhesives, and thus bronchoscopist will not aware of the patient group. Patient satisfaction will be measured in the recovery room and by the unaware nurse to the patient's group.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Imam Khomeini Hospital Complex - Tehran University of Science
Street address
Gharib st , Keshavarz Blvd. - Imam Khomeini Hospital Complex
City
Tehran
Province
Tehran
Postal code
1419733141
Approval date
2018-08-08, 1397/05/17
Ethics committee reference number
IR.TUMS.IKHC.REC.1397.122

Health conditions studied

1

Description of health condition studied
Comparison of patient satisfaction during flexible bronchoscopy by local anesthesia done with lidocaine spraying or conjunctive use of airway neural block and lidocaine spraying
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Patient Satisfaction Scale
Timepoint
After the patient's complete consciousness in the recovery room
Method of measurement
Visual numeric scale

Secondary outcomes

empty

Intervention groups

1

Description
Control group: In control group, local anesthetic agent in form of lidocain solution 1% will be sprayed in certain points so called "spray as you go" method. In this

method, 1% lidocaine solution will be sprayed on the vocal cords (4 milliliter), right main bronchus (2 milliliter) and left main bronchus (2 milliliter) through working channel of bronchoscope. In case of insufficiency and patient discomfort, another 2 milliliter of lidocaine 1% would be sprayed as bolus agent where needed.

Category

Other

2

Description

Intervention group: In the intervention group,Airway Nerve Block(ANB) will be added to the "spray as you go" method, . In ANB, three milliliters of lidocaine 1% will be injected into the cricothyroid membrane (to block recurrent laryngeal nerve) and another 1.5 milliliters of lidocaine 1% will be utilized on both sides of the neck to block the superior laryngeal nerve.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital - Tehran University of Medical Science

Full name of responsible person

Dr. Mehrnaz Asadi Gharabaghi

Street address

Imam Khomeini Hospital,Gharib St,Keshavarz Boulevard

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asadi_m@tumc.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mehrnaz Asadi Gharebaghi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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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

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available