

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Investigating the effects of the simultaneous administration of transtracheal block and topical anesthesia of glossopharyngeal nerve on hemodynamic change during intubation in awake patients with laryngeal cancer

Protocol summary

Study aim

Determining the effect of simultaneous transtracheal nerve block and topical anesthesia on hemodynamic changes during awake intubation

Design

A randomized clinical trial, 30 cases and 30 controls

Settings and conduct

Before intubation, the following will be pursued: Electrocardiography, Blood pressure measurement, Pulse oximetry, Secure IV line, Ringer lactate, Glycopyrrolate administration 0.2 mg before the procedure, Midazolam administration 1 mg 5 min before the procedure, Butorphanol administration 2 mg right before the procedure, Spraying 40 mg Lidocaine 10% in the oropharynx. A BP of 120/80 up to 140 /90 and a heart rate of 60-100 will be considered the normal range. The intervention will be conducted once. 30 patients in the intervention group will undergo Simultaneous transtracheal block and topical anesthesia of the glossopharyngeal nerve during awake intubation and 30 patients will receive topical glossopharyngeal nerve block as the control group. For transtracheal nerve block, a needle will penetrate the cricothyroid membrane and after aspiration, 4 ccs of lidocaine 2% will be injected. For topical anesthesia, topical lidocaine 10% will be sprayed 5 puffs at the posterior of the tongue bilaterally and at pharyngeal folds.

Participants/Inclusion and exclusion criteria

Patients with laryngeal cancer will be interviewed for inclusion and those who voluntarily fill out the informed consent form will be found eligible for inclusion. Those with a past history of asthma, allergy, or under anticoagulants will be excluded. Those with unstable hemodynamic changes such as bradycardia will be excluded. Patients with active infections will be excluded.

Intervention groups

Simultaneous transtracheal block and topical anesthesia of glossopharyngeal nerve during awake intubation

Main outcome variables

Changes in patients' blood pressure, heart rate, and oxygen saturation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220518054912N1**

Registration date: **2022-06-29, 1401/04/08**

Registration timing: **prospective**

Last update: **2022-06-29, 1401/04/08**

Update count: **0**

Registration date

2022-06-29, 1401/04/08

Registrant information

Name

pedram sarlaki

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2286 1226

Email address

pedramsarlaki@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-06, 1401/04/15

Expected recruitment end date

2022-07-21, 1401/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effects of the simultaneous administration of transtracheal block and tropical anesthesia of glossopharyngeal nerve on hemodynamic change during intubation in awake patients with laryngeal cancer

Public title

The effects of the simultaneous administration of transtracheal block and tropical anesthesia of glossopharyngeal nerve on hemodynamic change during intubation in awake patients with laryngeal cancer

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with laryngeal cancer who are candidates for awake intubation

Exclusion criteria:

Patients with a history of asthma or allergy or under anticoagulants Patients with unstable hemodynamic status (such as bradycardia) Patients with active infections

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Individual simple randomization, conducted using random numbers chart, and assigning random numbers to patients with 30 patients randomly assigned to the intervention group and 30 patients will be randomly assigned to the control group.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Factorial

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tehran University of Medical Sciences

Street address

Keshavarz boulevard, Central building of the Tehran University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2021-06-06, 1400/03/16

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.234

Health conditions studied**1****Description of health condition studied**

Laryngeal Cancer

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Changes in pulse rate, oxygen saturation level, and blood pressure during awake intubation in patients with laryngeal cancer

Timepoint

During the intervention

Method of measurement

Barometer and pulse oximeter

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Simultaneous administration of trans-tracheal nerve block and topical anesthesia on glossopharyngeal nerve

Category

Treatment - Other

2**Description**

Control group: Glossopharyngeal nerve block with oral injection of the Lidocaine 2%

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

AmirAlam Hospital Complex

Full name of responsible person

Pedram Sarlaki

Street address

Enghelab Ave., North Saadi Street

City

Tehran

Province

Tehran

Postal code

1145765111

Phone

+98 21 6670 8103

Email

Amiralam.ipd@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Nader Ali Nazemian Yazdi

Street address

Anesthesia Department of AmirAlam Hospital, North Saadi Street

City

Tehran

Province

Tehran

Postal code

1145765111

Phone

+98 21 6634 3352

Email

hamiralam@sina.tums.ac.ir

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

Pedram Sarlaki

Position

Student

Latest degree

Master

Other areas of specialty/work

Anesthesiology

Street address

No 8 . negarestan 4. Pasdaran Ave

City

Tehran

Province

Tehran

Postal code

1946964115

Phone

+98 21 2286 1226

Fax

Email

pedramsarlaki@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Pedram Sarlaki

Position

Student

Latest degree

Master

Other areas of specialty/work

Anesthesiology

Street address

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Postal code

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Phone

+98 21 2286 1226

Fax

Email

pedramsarlaki@yahoo.com

Person responsible for updating data

pedramsarlaki@yahoo.com

Contact

Name of organization / entity

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Phone

+98 21 2286 1226

Fax**Email**

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

Not applicable