Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of supra-laryngeal nerve block by sonography guided rout and conventional rout for direct laryngoscopy surgeries in supraglottic mass biopsy

Protocol summary

Study aim
Comparison of supra-laryngeal nerve block by sonography guided rout and conventional rout for direct laryngoscopy surgeries in supraglottic mass biopsy

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, on 48 patients. In order to randomize, the block randomization method will be used.

Settings and conduct
The study will be done on all patients referred to Hazrat Rasoul Hospital. The study will be double blind in which patients, therapists and data analysts will be blind. Patients will be unaware of which treatment will be offered in that group. The therapist will not know which method will be used for each patient. The analyst will also analyze the information based on groups 1 and 2 and will not know the type of treatment provided in the groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients referred to the of Hazrat Rasoul Akram Hospital, who needed direct laryngoscopy surgeries in supraglottic masses biopsy; Patients over 18 years; Patients with BMI below 30. Non-inclusion criteria: Coagulation disorders; History of seizures; Disorders of consciousness and delirium; Hypersensitivity to lidocaine; Inability to move the neck; Patients over 70 years.

Intervention groups
Intervention group: Supra-laryngeal nerve block by sonography: In the ultrasound technique, the probe is placed in the submandibular region, between the GHH bone and the thyroid cartilage above the hyoid space, 2 cc of lidocaine 2% is injected with gauge 23 needle. Control group: The laryngoscope is inserted through the mouth and driven into the larynx through the tongue so that the vocal cords are visible.

Main outcome variables
Patient's Satisfaction; Surgeon's satisfaction; Block's Hematoma

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191003044963N1**
Registration date: **2020-06-01, 1399/03/12**
Registration timing: **prospective**

Last update: **2020-06-01, 1399/03/12**
Update count: **0**

Registration date
2020-06-01, 1399/03/12

Registrant information

Name
Salume Sehat kashani

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 2205 5066

Email address
sehat.s@iums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-06-09, 1399/03/20

Expected recruitment end date
2021-06-10, 1400/03/20

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of supra-laryngeal nerve block by sonography guided rout and conventional rout for direct laryngoscopy surgeries in supraglottic mass biopsy

Public title

Comparison of supra-laryngeal nerve block by sonography guided rout and conventional rout

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients referred to the of Hazrat Rasoul Akram Hospital, who needed direct laryngoscopy surgeries in supraglottic masses biopsy Patients over 18 years old BMI below 30

Exclusion criteria:

Coagulation disorders History of seizures Disorders of consciousness and delirium Hypersensitivity to lidocaine Inability to move the neck Patients over 70 years

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly assigned to two groups. In order to randomize, a random block method will be used. For this purpose, we formed blocks of size 6. In each block, 3 individuals will be in intervention group and 3 will be in control group. A total of 8 blocks will be considered for the study.

Blinding (investigator's opinion)

Double blinded

Blinding description

Data will be analyzed by person who is blind to study groups. The therapist and patients will also be unaware of the type of treatment. Patients will be aware that they will be randomly assigned to one of two treatment groups, but will be unaware of which treatment will be provided in that group. Patients will be assigned to one of two groups using random number tables. The therapist also knows that patients will be treated with two different methods of supra-laryngeal nerve block, but will not know which method will be performed for each patient. The analyst will also analyze the information based on groups 1 and 2 and will not have the type of treatment offered in the groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Hemmat Highway

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2020-02-04, 1398/11/15

Ethics committee reference number

IR.IUMS.FMD.REC.1398.490

Health conditions studied

1

Description of health condition studied

Supraglottic mass

ICD-10 code

J04.3

ICD-10 code description

Supraglottitis, unspecified

Primary outcomes

1

Description

Patient's Satisfaction

Timepoint

End of surgery

Method of measurement

From 1 to 5 (based on Likert scale) by questionnaire

2

Description

Surgeon's satisfaction

Timepoint

End of surgery

Method of measurement

From 1 to 5 (based on Likert scale) by questionnaire

3

Description
Block's Hematoma
Timepoint
End of surgery
Method of measurement
Based on patient records

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the ultrasound technique, the probe is placed in the submandibular region and the GHH bone is diagnosed along with the thyroid cartilage. Between the GHH bone and the thyroid cartilage above the hyoid space, 2 cc of lidocaine 2% is injected with gauge 23 needle.
Category
Treatment - Surgery

2

Description
Control group: The laryngoscope is inserted through the mouth and driven into the larynx through the tongue so that the vocal cords are visible.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazrat Rasoul Akram hospital
Full name of responsible person
Parvaneh Zandi
Street address
Hazrate Rasool hospital, Niyayesh street, Sattarkhan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Salomeh Sehat Kashani
Position
Assistant Professor of Anesthesiology and Special Care
Latest degree
Specialist
Other areas of specialty/work
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Position
Assistant Professor of Anesthesiology and Special Care

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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