

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

Efficacy of the sono-guided superficial cervical plexus block on post operative pain of tympanomastoidectomy surgery: A double blind randomized Study

Protocol summary

Study aim

Control of pain after tympanomastoidectomy surgery

Design

In this study, 100 candidates for tympanomastoidectomy who are referred to the Amiralam hospital in the age group of 18 to 60 years old are selected. Patients are randomly assigned to cervical plexus and placebo groups using 4 block size.

Settings and conduct

In this study, 100 patients who are candidates for tympanomastoidectomy are referred to the AmirAlam Hospital. Patients are randomly assigned to four equal blocks of cervical plexus and placebo using quadruple blocks. In order to blind, the block syringe for the block is prepared by an anesthetist and without an anesthetist's anesthetist who is making a block based on random numbers. Also, ensuring the success of the block in the case group is measured by a collaborator's anesthesiologist by the Pin Prick test and in the case of The failure of the block in the use of the anesthetic substance of the patient is excluded from the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Patients undergoing thyroidectomy surgery 2. Age between 18 and 60 years Exclusion criteria: 1. Sensitivity to topical anesthetic drugs 2. Failure of superficial cervical cord block 3. Changed neck anatomy 4. Local infection

Intervention groups

The intervention group included an ultrasound superficial cervical plexus block based on anatomical landmark bilaterally in the posterior region of the middle part of the sternocleidomastoid muscle with ten cc of ropivacaine plus epinephrine 1/200.000 . In the control group instead of ropivacaine as the local anesthetic 10 cc normal saline as a placebo is used to inject.

Main outcome variables

post operation pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170826035905N2**

Registration date: **2018-01-13, 1396/10/23**

Registration timing: **prospective**

Last update: **2018-01-13, 1396/10/23**

Update count: **0**

Registration date

2018-01-13, 1396/10/23

Registrant information

Name

Nader Ali Nazemian Yazdi

Name of organization / entity

Tehran University of Medical Sciences/Amir Alam Hospital

Country

Iran (Islamic Republic of)

Phone

+98 21 8830 3621

Email address

nnazemian@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-21, 1396/11/01

Expected recruitment end date

2019-03-21, 1398/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of the sono-guided superficial cervical plexus block on post operative pain of tympanomastoidectomy surgery: A double blind randomized Study

Public title

Control of pain after tympanomastoidectomy Surgery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients undergoing tympanomastoidectomy surgery
Age between 18 and 60 years

Exclusion criteria:

Sensitivity to topical anesthetic drugs
Failure of superficial cervical cord block
Changed neck anatomy
Local infection

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done by 4 block size

Blinding (investigator's opinion)

Double blinded

Blinding description

After dividing the patients into two groups, the case group after the sedation and before induction of general anesthesia under an ultrasound superficial cervical plexus block based on anatomical landmark bilaterally in the posterior region of the middle part of the sternocleidomastoid muscle with ten cc of ropivacaine plus epinephrine 1/200.000. In order to blindness of the study, the syringe content drug for block is prepared by a nurse anesthetist and anesthesiologist is not aware about syringe content. Nurse anesthetist is making a block based on random numbers and the only person aware of the contents of the syringe.

Placebo

Used

Assignment

Parallel

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

Corner of Ghods Street, Keshavarz Boulevard

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2017-09-02, 1396/06/11

Ethics committee reference number

IR.TUMS.VCR.REC.1396.3307

Health conditions studied

1

Description of health condition studied

post tympanomastoidectomy pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Post operation pain

Timepoint

2,6,12,24 hours after the surgery

Method of measurement

Pain measure ruler

Secondary outcomes

1

Description

Nausea and vomitting

Timepoint

2,6,12,24 hours after surgery

Method of measurement

Ask from patient and nurse

2

Description

The amount of analgesic use after surgery

Timepoint

2,6,12,24 hours after surgery

Method of measurement

Nursing report

3

Description

Remifentanyl consumption during operation

Timepoint

End of the operation

Method of measurement

Anesthesia report paper

Intervention groups

1

Description

Intervention group: The intervention group included an ultrasound superficial cervical plexus block based on anatomical landmark bilaterally in the posterior region of the middle part of the sternocleidomastoid muscle with ten cc of 0.2% ropivacaine plus epinephrine 1/200.000 .

Category

Treatment - Drugs

2

Description

Control group: Control group: In the control group instead of ropivacaine as the local anesthetic; 10 cc normal saline as a placebo is used to inject.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

AmirAlam Hospital

Full name of responsible person

Dr Nader Ali Nazemian Yazdi

Street address

AmirAlam Hospital, North Saadi Street, Enghelab Avenue

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drnnazemian@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellorfor Research of Tehran University of Medical Sciences

Full name of responsible person

Dr MohammAli Sahraeian

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Corner of Ghods Street, Keshavarz Boulevard

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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

Vice Chancellorfor Research of 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 Nader Ali Nazemian Yazdi

Position

Assistant professor of Anesthesiology

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr Nader Ali Nazemian Yazdi

Position

Assistant professor of Anesthesiology

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Subspecialist

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

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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

Not applicable

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

Not applicable

Data Dictionary

Not applicable