

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of Peritonsillar injection of mixture of Dexmedetomidine-Ropivacaine and tramadol - Ropivacaine in postoperative pain control and sedation after tonsillectomy under general anesthesia

Protocol summary

Study aim

Comparison of Peritonsillar injection of mixture of Dexmedetomidine- Ropivacaine and tramadol - Ropivacaine in postoperative pain control and sedation after tonsillectomy under general anesthesia

Design

The study will be double blind and clinical trial.99 patients will be randomly divide into 3 groups. The groups are parallel. The trial phase is 3.

Settings and conduct

Patients with tonsillectomy surgery under general anesthesia in Valiasr hospital in Arak are divided into 3 groups by simple randomization with envelopes. The study is double-blind in which outcome evaluator and data analyst and participant are kept blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria:Candidate for tonsillectomy, no metabolic glandular disease, no coagulation disease, no mental retardation, absence of peritonsillar, absence of hypertension, absence of psychotic disorder, absence of chronic pain Exclusion criteria:Dissatisfaction with the patient or parents' own surgery

Intervention groups

Dexmedetomidine and Ropivacaine group: 5 millilitre of a solution containing Ropivacaine 0.25% and 1 µg / kg of dexmedetomidine will be injected as a peritonsillar. (Dexmedetomidine made by Elixir Company - Iran)
Tramadol and Ropivacaine group: 5 millilitre of solution containing Ropivacaine 0.25% and 2 mg per kg of tramadol (manufactured by Caspian Tamin Iran - Rasht) will be injected as a peritonsilla. Placebo and Ropivacaine group: 5 millilitre of 25% Ropivacaine solution with normal saline will be injected as a peritonsilla.

Main outcome variables

Sedation, pain, total dose of narcotics

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N163**

Registration date: **2021-07-18, 1400/04/27**

Registration timing: **prospective**

Last update: **2021-07-18, 1400/04/27**

Update count: **0**

Registration date

2021-07-18, 1400/04/27

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-23, 1400/05/01

Expected recruitment end date

2022-07-23, 1401/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Peritonsillar injection of mixture of Dexmedetomidine- Ropivacaine and tramadol - Ropivacaine in postoperative pain control and sedation after tonsillectomy under general anesthesia

Public title

Comparison of Peritonsillar injection of mixture of Dexmedetomidine- Ropivacaine and tramadol - Ropivacaine in postoperative pain control and sedation after tonsillectomy under general anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Candidate for tonsillectomy No metabolic glandular disease No coagulation disease No mental retardation Absence of peritonsillar abscess Absence of hypertension Absence of psychotic disorder Absence of chronic pain

Exclusion criteria:

Dissatisfaction with the patient or parents' own surgery

Age

From **3 years** old to **12 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **99**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple individual randomization with random allocation with envelopes in 3 groups A and B and C. In this method, we selected a number of cards or letters as an intervention group and the same number of cards for the control group, then the cards were merged. One card was taken out and its allocation was registered and the card was returned to the other cards after leaving. Then the cards are merged again and we remove another card. This process continues to reach a random sequence according to sample size.

Blinding (investigator's opinion)

Double blinded

Blinding description

In terms of patient blindness, the complementary intern does not know the groupings, and general anesthesia and drug injections are performed by an anesthesiologist. Outcome assessor and data analyzer and participant are blind (double blind). Outcome assessor and data analyzer and participant don't aware from grouping. The intern is unaware of the drugs prescribed in each group and the anesthesiologist prepares the drugs and provides them to the intern. Also, the patients do not know about their group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Ethics committee, Research center, Payambar Azam complex, Basij square, Sardasht, Arak

City

Arak

Province

Markazi

Postal code

3848176941

Approval date

2021-05-30, 1400/03/09

Ethics committee reference number

IR.ARAKMU.REC.1400.040

Health conditions studied

1

Description of health condition studied

Tonsillectomy

ICD-10 code

J03.9

ICD-10 code description

Acute tonsillitis, unspecified

Primary outcomes

1

Description

Sedation

Timepoint

5 minutes, 15 minutes, 30 minutes, 1, 2, 4, 6, 12 and 24 hours after surgery

Method of measurement

Wilson sedation scale

2

Description

Pain

Timepoint

At 5 minutes, 15 minutes, 30 minutes, 1, 2, 4, 6, 12 and 24 hours after surgery

Method of measurement

Oucher scale

3

Description

Total dose of narcotics

Timepoint

24 hours after surgery

Method of measurement

Hospital file

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1: 5 millilitre of a solution containing Ropivacaine 0.25% and 1 µg / kg of dexmedetomidine will be injected as a peritonsillar. (Dexmedetomidine made by Elixir Company - Iran)

Category

Treatment - Drugs

2

Description

Intervention group2: 5 millilitre of solution containing Ropivacaine 0.25% and 2 mg per kg of tramadol (manufactured by Caspian Tamin Iran - Rasht) will be injected as a peritonsilla.

Category

Treatment - Drugs

3

Description

Control group: 5 millilitre of 25% Ropivacaine solution with normal saline will be injected as a peritonsilla.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amirkabir hospital

Full name of responsible person

Dr Hesamodin Modir

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Amirkabir hospital, Parastar square, Arak

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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

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Dr Esmaeel Moshiri

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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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