Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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Name of organization / entity

Arak University of Medical Sciences

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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 comittee of Arak University of Medical Sciences

Street address
Ethics comittee, Research center, Payambar Azam complex, Basij squre ,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

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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
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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