

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Evaluation of effects of Gabapentin, Dexamethasone and Ropivacaine on pain after tonsillectomy surgery in adult patients.

Protocol summary

Study aim

Evaluation of effects of Gabapentin, Dexamethasone and Ropivacaine on pain after tonsillectomy surgery in adult patients.

Design

In the present double-blind clinical trial, which will be carried out in a parallel way, a total of 50 patients who will be undergoing tonsillectomy surgery will be enrolled. Eligible patients will be randomly allocated into two equal A and B groups by block randomization.

Settings and conduct

Patients who are candidates for tonsillectomy surgery who visit Dena Hospital in Shiraz during the study will be included in the study if they are eligible and will be randomly assigned to the intervention and control groups using the random block method. This study will be conducted in a double-blind manner, so that the patients and the examining physician and the outcome assessor will not know the type of intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Adult patients with ASA grade I or II, patients between 18 and 40 years old, Body mass index between 18 and 25, Candidate for tonsillectomy surgery and The distance between the hospital and the patient's place of residence should be a maximum of 30 minutes by car. Exclusion criteria: Allergy to the drugs used in the study Positive history of liver, kidney, Coagulation disorders, uncontrolled diseases of the cardiovascular system, Obstructive sleep apnoea and Addiction to drugs.

Intervention groups

Intervention group: Patients will use 300 mg of Gabapentin orally three days before the operation. After anesthesia, they will receive 8 mg of Dexamethasone and 4 ml of half percent Ropivacaine solution. Control group: Patients will receive capsules similar to Gabapentin (in appearance) as a placebo three days before the operation. After anesthesia, they will receive 2 ml of distilled water and 4 ml of normal saline in similar

syringes.

Main outcome variables

Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100127003213N10**

Registration date: **2023-05-14, 1402/02/24**

Registration timing: **prospective**

Last update: **2023-05-14, 1402/02/24**

Update count: **0**

Registration date

2023-05-14, 1402/02/24

Registrant information

Name

Arash Farbood

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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farboda@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-01, 1402/03/11

Expected recruitment end date

2024-02-01, 1402/11/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of effects of Gabapentin, Dexamethasone and Ropivacaine on pain after tonsillectomy surgery in adult patients.

Public title

Evaluation of effects of Gabapentin, Dexamethasone and Ropivacaine on tonsillectomy pain in adults.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Adult patients with ASA grade I or II (American Society of Anesthesiology classification) patients between 18 and 40 years old Body mass index (BMI) between 18 and 25 Candidate for tonsillectomy or adenotonsillectomy with diagnosis of tonsillitis The distance between the hospital and the patient's place of residence should be a maximum of 30 minutes by car

Exclusion criteria:

Allergy to the drugs used in the study Positive history of liver, kidney, Coagulation disorders, Diseases of the digestive system, depression and anxiety Positive history of uncontrolled diseases of the cardiovascular system Addiction to drugs Obstructive sleep apnoea Taking painkillers other than study drugs in 24 hours before surgery

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly allocated into two groups by block randomization. In this technique, a permutation block of size 10 will be made for patients of two groups A & B. In each block, equal numbers for two groups will be considered in alternative positions. Then 5 blocks of size 10 will be selected randomly and patients will be allocated randomly and equally into three groups according to these permutation block. block sequence will be prepare by www.sealedenvelope.com.

Blinding (investigator's opinion)

Double blinded

Blinding description

In the intervention group, patients will use 300 mg of Gabapentin orally three days before the operation, while

patients in the control group will receive capsules similar to Gabapentin (in terms of appearance) and as a placebo. In the operating room, all study drugs will be provided by the only person familiar with the study (Nurse anesthetist). The anesthesiologist, patients, and other personnel involved in the work are blinded to the drugs injected in this study. This study is double-blind.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Shiraz Medical School

Street address

3rd Floor, 3rd buiding of the Shiraz Medical School, Zand Blvd.

City

Shiraz

Province

Fars

Postal code

7134844119

Approval date

2023-03-05, 1401/12/14

Ethics committee reference number

IR.SUMS.MED.REC.1401.584

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**

Pain

Timepoint

Every 15 minutes in the recovery room and three times a day (morning, noon and night) for ten days.

Method of measurement

Visual Analog Scale for Pain

Secondary outcomes

1

Description

The quality of the patient's sleep

Timepoint

Every day for ten days

Method of measurement

In respect to standardized questionnaire

2

Description

The first time to start normal food

Timepoint

Every day for ten days

Method of measurement

Patient history taking

3

Description

Patient satisfaction rate

Timepoint

Every day for ten days

Method of measurement

In respect to standardized questionnaire

Intervention groups

1

Description

Intervention group: Patients will use 300 mg of Gabapentin orally three times a day three days before the operation, and this regimen will continue until ten days after the operation. The anesthesia induction method will be similar in the two study groups. After anesthesia, patients in the intervention group will receive 8 mg of Dexamethasone intravenously. At the end of the surgery, the surgeon will inject 4 ml of half percent Ropivacaine solution in the tonsil cavity and its surrounding areas on each side. In both study groups, postoperative patients will receive a basic analgesic regimen including Acetaminophen 325 mg four times a day and Celecoxib 200 mg twice a day for one week. In addition, 5 mg Oxycodone tablets will be provided to them so that they can take one when the pain worsens.

Category

Treatment - Drugs

2

Description

Control group: Patients in the control group will receive capsules similar to Gabapentin (in appearance) with the same drug regimen as placebo three days before surgery. After anesthesia, the patients of the control group will receive 2 ml of distilled water in the same syringe and intravenously, and at the end of the surgery, the injections will be performed by the surgeon with the

same syringe and the same volume of normal saline. In both study groups, postoperative patients will receive a basic analgesic regimen including Acetaminophen 325 mg four times a day and Celecoxib 200 mg twice a day for one week. In addition, 5 mg Oxycodone tablets will be provided to them so that they can take one when the pain worsens.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dena Hospital

Full name of responsible person

Ali Mohebpour

Street address

Dena Hospital, Blvd-E-Sattar Khan, Zargari Blvd.

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7186764951

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mohammad hashem Hashempour

Street address

7th floor, central building of Shiraz University of Medical Sciences, Vice Chancellor of research, Zand street.

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

No

Title of funding source

Shiraz 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**

Shiraz University of Medical Sciences

Full name of responsible person

Ali Mohebpour

Position

Anesthesiology resident/physician

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Arash Farbood

Position

Anesthesiologist/Pain Fellowship

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Hamide Saeedizade

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Research Assistant

Latest degree

Bachelor

Other areas of specialty/work

Medical Informatics

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

It is against our policy.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available