Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 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

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Iran (Islamic Republic of)

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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
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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
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Person responsible for updating data

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saeedi.hamide@gmail.com

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