

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

A clinical trial on the effects of promethazine and gabapentin as pre-medication in reducing postoperative pain in 7- to 9-year-old patients undergoing tonsillectomy

Protocol summary

Summary

This study compares the effects of promethazine and gabapentin as premedication on postoperative pain reduction in tonsillectomy. A total of 104 patients aged from 7 to 15 years undergoing tonsillectomy who have inclusion criteria (non-addiction to and non-use of psychotropic and psychoactive drugs; no history of anxiety, neuropsychiatric, and hyperactivity disorders or chronic pain) will be incorporated upon provision of informed consent. The study is double-blind and will be performed in the second phase of clinical trial. Prior to complete anesthesia, the participants will be allocated into gabapentin or promethazine groups via simple allocation method (n = 52 per group). The gabapentin group receives 20 milligrams per kilogram along with 50 cc of water one hour before anesthesia. The promethazine group receives 0.5 cc per kilogram and up to a maximum dose of 25 milligram promethazine syrup orally one hour before anesthesia. Postoperative pain at 3, 6, 12 and 24 hours after the operation will be measured using the Medical Objective Pain Scale in both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017051517756N14**
Registration date: **2017-07-05, 1396/04/14**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-07-05, 1396/04/14

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice-chancellery for Research of Birjand University of Medical Sciences

Expected recruitment start date

2017-07-23, 1396/05/01

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial on the effects of promethazine and gabapentin as pre-medication in reducing postoperative pain in 7- to 9-year-old patients undergoing tonsillectomy

Public title

Comparing the effects of promethazine and gabapentin as premedication in reducing pain in tonsillectomy operation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: non-addiction to and non-use of psychotropic and psychoactive drugs; no history of anxiety, neuropsychiatric, and hyperactivity disorders or chronic pain; age between 7 and 15 years; patient referred by the ENT specialist, co-researcher in this project; non-use of drugs effective on heart rate and pressure; informed consent. Exclusion criteria: Surgery length over 30 minutes; complications during or after surgery, e.g., bleeding and hypoxia

Age

From **7 years** old to **15 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **104**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Birjand University of Medical Sciences

Street address

Vice-chancellery for Research, Birjand University of Medical Sciences, Ghaffari St.,

City

Birjand,

Postal code**Approval date**

2017-05-01, 1396/02/11

Ethics committee reference number

lr.bums.REC.1396.32

Health conditions studied**1****Description of health condition studied**

Post-operative pain

ICD-10 code

R07.0

ICD-10 code description

Pain in throat

Primary outcomes**1****Description**

Pain severity

Timepoint

3, 6, 12 and 24 hours after operation

Method of measurement

Medical Objective Pain Scale

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention Group 1 (Gabapentin group): The gabapentin group receives 20 milligrams per kilogram along with 50 cc of water one hour before anesthesia. Postoperative pain at 3, 6, 12 and 24 hours after the operation will be measured using the Medical Objective Pain Scale.

Category

Treatment - Drugs

2**Description**

Intervention Group 2 (The promethazine group): The group receives 0.5 cc per kilogram and up to a maximum dose of 25 milligram promethazine syrup orally one hour before anesthesia. Postoperative pain at 3, 6, 12 and 24 hours after the operation will be measured using the Medical Objective Pain Scale.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Valiasr Hospital

Full name of responsible person

Masoud Madihi

Street address

Ghafari Street,

City

Birjand,

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellery for Research, Birjand University of Medical Sciences

Full name of responsible person

Dr Tooba Kazemi

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Vice chancellor for research, Birjand University of Medical Sciences, Ayatollah Ghafari Street,

City

Birjand,

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice-chancellery for Research, Birjand University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

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Position

PhD Candidate in Translation Studies

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty