

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

Effect of gabapentin on the prevention of emergence agitation in children after general anesthesia

Protocol summary

2021-02-17, 1399/11/29

Study aim

Effect of gabapentin on the prevention of emergence agitation in children after general anesthesia

Design

Double-blind randomized clinical trial

Settings and conduct

Intervention group: 15 mg / kg of gabapentin is dissolved in 10 cc of water and given to the children in the case group one hour before entering the operating room.
Control group: Water (placebo) is given to the control group with equal volume of case group.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Children under the age of twelve
Children candidates for tonsillectomy
Exclusion Criteria:
History of heart, liver, kidney, mental diseases
Contraindications to the use of gabapentin
History of seizures

Intervention groups

Intervention group: 15 mg / kg of gabapentin is dissolved in 10 cc of water and given to the children in the case group one hour before entering the operating room.
Control group: Water (placebo) is given to the control group with equal volume of case group.

Main outcome variables

Agitation, Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141009019470N111**
Registration date: **2021-02-17, 1399/11/29**
Registration timing: **prospective**

Last update: **2021-02-17, 1399/11/29**

Update count: **0**

Registration date

Registrant information

Name

Farzaneh Masihi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 4270

Email address

masihif@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-27, 1399/12/09

Expected recruitment end date

2021-05-11, 1400/02/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of gabapentin on the prevention of emergence agitation in children after general anesthesia

Public title

Effect of gabapentin on the prevention of emergence agitation in children after general anesthesia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Children under the age of twelve
Children candidates for tonsillectomy

Exclusion criteria:

History of heart, liver, kidney, mental diseases
Contraindications to the use of gabapentin History of seizures

Age

To 12 years old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: 132

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is performed for the two intervention and control groups by using 4, 6 and 8 permutation blocks extracted from the site www.sealedenvelope.com.

Blinding (investigator's opinion)

Double blinded

Blinding description

One hour before entering the operating room, 15 mg / kg of gabapentin is dissolved in 10 cc of water and given to the children of the case group and given to the control group (placebo) in equal volume.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

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

City

Shiraz

Province

Fars

Postal code

7134844119

Approval date

2016-09-28, 1395/07/07

Ethics committee reference number

IR.SUMS.MED.REC.1395.s101

Health conditions studied

1

Description of health condition studied

Tonsillectomy

ICD-10 code

J03.00

ICD-10 code description

Acute streptococcal tonsillitis, unspecified

Primary outcomes

1

Description

Agitation

Timepoint

Time intervals 0,5,15,30,45,60 minutes after entering the recovery

Method of measurement

Watcha Scale

2

Description

Pain

Timepoint

Time intervals 0,5,15,30,45,60 minutes after entering the recovery

Method of measurement

Wong-baker faces Scale

Secondary outcomes

1

Description

Heart Rate

Timepoint

Time intervals 0,5,15,30,45,60 minutes after entering the recovery

Method of measurement

Monitoring

Intervention groups

1

Description

Intervention group: 15 mg / kg of gabapentin is dissolved in 10 cc of water and given to the children in the case group one hour before entering the operating room.

Category

Prevention

2

Description

Control group: Water (placebo) is given to the control group with equal volume of case group.

Category

Placebo

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

Khalili Hospital

Full name of responsible person

Sayed Khademi

Street address

Khalili St, Khalili Educational and Medical Center

City

Shiraz

Province

Fars

Postal code

1433671348

Phone

+98 71 3629 1470

Email

khalili@sums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Abbas Rezaieanzadeh

Street address

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

City

Shiraz

Province

Fars

Postal code

7134844119

Phone

+98 71 3647 4270

Email

vcrd@sums.ac.ir

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

Yes

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

Saied Khademi

Position

Anesthesiologist

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Anesthesiology Department, Faghihi Hospital, Zand Street

City

Shiraz

Province

Fars

Postal code

7134844119

Phone

+98 71 3647 4270

Email

saied.khademi@gmail.com

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

Shiraz University of Medical Sciences

Full name of responsible person

Saied Khademi

Position

Anesthesiologist

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Anesthesiology Department, Faghihi Hospital, Zand Street

City

Shiraz

Province

Fars

Postal code

Anesthesiology Depar

Phone

+98 71 3647 4270

Email

saied.khademi@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Farzaneh Masihi

Position

BS in anesthesia/English Consultant

Latest degree

Master

Other areas of specialty/work

Anesthesiology

Street address

Anesthesiology Department, Namazi Hospital, Namazi square

City

Shiraz

Province

Fars

Postal code

7134844119

Phone

+98 71 3647 4270

Email

masihifarzaneh@yahoo.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

Its against our polices.

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