Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

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

Protocol summary

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
2021-02-17, 1399/11/29

Registrant information
Name
Farzaneh Masihi
Name of organization / entity
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Iran (Islamic Republic of)
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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

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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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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

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Person responsible for updating data

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Full name of responsible person
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Position
BS in anesthesia/English Consultant

Latest degree
Master

Other areas of specialty/work
Anesthesiology

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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
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