Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Nov 2026

Effect of gabapentin and acetapinophen susspention on postoperative pain after adenotonsilcetomy

Protocol summary

Summary

The purpose of this study was comparision effect of gabapentin and sup of acetaminophen in control of postoperative pain and nausea and vomiting.the main inclusion criteria included all children 7-15 years old candidate for adenotonsilectomy surgery and with recurrent and chronic tonsilitis , and exclusion criteria incluced history of seizure and gabapantin usage and taking pain killers in last 24 hours. the patients divided in to 30 member groups. In first groups childs recived 10/mg/kg, gabapentin 2 hour before anesthesia and second group recived acetaminophen after maintenance of anesthesia. Both groups anesthetized in same manner then before induction of anesthesia and in 2,4,6,12,24 hour after operation both group were studied for existence of nausea and vomiting ,types of drugs used ,their dosage and degree of pain. Outside following time intervals if patients were complaining for pain or nausea and vomiting they were treated according to protocol. Paitents were monitored for vital signs and respiratory after operation , and in case of hypotension there were treated by ephedrine and in case of respiratiory depression they received oxygen by ambobag and ventilation .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016102115963N7**
Registration date: **2017-02-01, 1395/11/13**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-02-01, 1395/11/13

Registrant information

Name
Soudabeh Haddadi
Name of organization / entity
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Recruitment status

Recruitment complete

Funding source
Guilan University of Medical Sciences, Vice Chancellor for Research

Expected recruitment start date

2016-10-31, 1395/08/10

Expected recruitment end date

2017-08-01, 1396/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of gabapentin and acetapinophen susspention on postoperative pain after adenotonsilcetomy

Public title

A survey comparing effect of gabapentin and acetaminophen suspention on postoperative pain after tonsil removal surgery in children reciveing these drugs

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria : 7-15 year old child candidate for adenotonsilectomy; Recurrent tonsillitis; chronic

tonsillitis; Obstructive sleep apnea; Breathing with open mouth; Snoring and dysphagia Exclusion criteria : Known allergy to gabapentin and acetaminophen ; History of sezuire and gabapentin usage; Renal or hepatic dysfunction; Usage of analgesic in last 24 hours; Opiod addiction; Known G6PD deficiency; Diarrhea and dehydration; Bleeding abnormality; operation lasting more then 90 min

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

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **60**

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 Guilan University of Medical Science

Street address
Vice-Chancellor for Research Building, Opposite of SepahBank,ShahidBeheshti Blvd, Rasht

City
Rasht

Postal code

Approval date
2016-08-13, 1395/05/23

Ethics committee reference number
IR.GUMS.REC.1395.157

Health conditions studied

1

Description of health condition studied
Acute tonsillitis

ICD-10 code
J03

ICD-10 code description
Acute tonsillitis

Primary outcomes

1

Description
Postoperative pain

Timepoint
2,4,6,12,24 hour after surgery

Method of measurement
Visual analog score

Secondary outcomes

1

Description
Nausea and vomiting

Timepoint
2,4,6,12,24 hour after operation

Method of measurement
Based on asking patients in time intervals

Intervention groups

1

Description
Control group: recived acetaminophen after maintenance of anesthesia. Both groups anesthetized in same manner

Category
Treatment - Drugs

2

Description
Interventional group: recieved gabapentin 10mg/kg 2 hour before anesthesia

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Amiralmomenin Hospital

Full name of responsible person
Dr Sudabeh Haddadi

Street address
Amiralmomenin Hospital, 17 Shahrivar St

City
Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Guilan University of Medical Science, Vice Chancellor for Research

Full name of responsible person
Susan Komaee

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Vice-Chancellor for Research Building, Opposite of SepahBank,ShahidBeheshti Blvd, Rasht

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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
Guilan University of Medical Science, Vice Chancellor for Research

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

Contact

Name of organization / entity
Guilan University of Medical Sciences

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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