Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Study of Acetaminophen and Dexamethasone effects on agitation in children undergoing tonsillectomy

Protocol summary

Study aim

1- Comparison of the effect of acetaminophen and dexamethasone on the rate of restlessness of children undergoing tonsillectomy. 2- Comparison of the effect of acetaminophen and dexamethasone on the degree of restlessness of children undergoing tonsillectomy based on age 3- Comparison of the effect of acetaminophen and dexamethasone on the degree of restlessness of children undergoing tonsillectomy by sex 4. Comparison of the effect of acetaminophen and dexamethasone drugs on the mean pain of children undergoing tonsillectomy

Design

In this study, 140 children undergoing tonsillectomy Referring to Khatam-al-Anbia Hospital in Zahedan having the inclusion criteria and double-blinded in phase 3 trial enters the study and divided into four categories with Simple random method And the codes are assigned to them.

Settings and conduct

Children aged 2 to 7 years undergoing tonsillectomy referring to Khatam Al-Nabia Hospital enters the study. Blinding double-blind method will be use and study groups members and expert statistical will not know the details of study groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 2 to 7 years, undergo tonsillectomy operation, parental consent for children Conditions not included in the study: taking previous medications (remove all previous medications 2 hours before surgery)

Intervention groups

Group 1: Dexamethasone and acetaminophen placebo (Dexamethasone intravenously and 0.2 mg / kg in addition with 0.25 mg / kg of syrup with strawberry flavor). Group 2: Acetaminophen and placebo of Dexamethasone (20 mg / kg) Acetaminophen with 0.5 ml / kg of normal saline serum. Group 3: Acetaminophen and Dexamethasone (20 mg / kg acetaminophen syrup) and dexamethasone intravenously (0.2mg / kg)). Group 4: Dexamethasone placebo and acetaminophen placebo (0.5ml / kg of normal saline plus 0.25mg / kg of syrup with strawberry flavor). Monitoring and control starts in the operation room, which includes the electrocardiogram, Pulse oximetry and blood pressure. After preoxygenation with 100% oxygen by mask, induction of anesthesia with atropine 0.01 mg / kg, 2 micg / kg fentanyl, 5 mg / kg sodium thiopental and 0.5 mg / kg atracurium. The tracheal intubation will performed and the immobilization will performed with 66% N2O at 33% O2 and 1/2 MAC of isoflurane. The number of breathing ventilators with CO2 output will set to between 35 mmHg and 45 mmHg. Morphine will injected 0.1 ml / kg intravenously to all patients after the endotracheal fixation. Each 1 ml of blood lost replaced with 3 ml of ringer lactate serum . When the child is able to open his eyes and keep the head up for 5 seconds, the tracheal tube will be out. In The PICU section, the children's restlessness will measured by Richmond Agitation Sedation Score after passing 10, 20 and 30 minutes of the extubation of the tube.

Main outcome variables

agitation : after intervention . After receiving the medication, the Richmond Agitation Sedation Score in the PICU section of the children's restraint is measured after 10, 20, and 30 minutes after the removal of the tracheal tube. (0: alert and quiet, 1: restless, 2: disturbed, 3: very disturbed and 4: controversy and fights) and pain is measured by Face Scale.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171016036817N1**
Registration date: **2017-12-22, 1396/10/01**
Registration timing: **registered_while_recruiting**

Last update: **2017-12-22, 1396/10/01**
Update count: **0**

Registration date
2017-12-22, 1396/10/01

Registrant information

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Recruitment status
Recruitment complete

Funding source
Investigator

Expected recruitment start date
2017-12-21, 1396/09/30

Expected recruitment end date
2018-08-22, 1397/05/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Study of Acetaminophen and Dexamethasone effects on agitation in children undergoing tonsillectomy

Public title
Effect of Acetaminophen and Dexamethasone on agitation in tonsillectomy children

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Parents are satisfied with entering the study All children aged 2 to 7 years undergoing tonsillectomy

Exclusion criteria:
Those who have taken previous medications (all previous medications should be removed within 2 hours before the surgery)

Age
From **2 years** old to **7 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **140**

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization and the entry of the statistical community into each intervention or control group will be based on the selection of colored papers, so that we will have four colors of blue, green, yellow and red papers for the sample size. Those who take the blue paper will enter the intervention group, those who take the green paper will go into the control group with the acetaminophen placebo, those who take the yellow paper will go into the control group with the dexamethasone placebo, and the those who take the red paper will enter the control group with the Both the placebo.

Blinding (investigator's opinion)
Double blinded

Blinding description
Each member of the control and intervention groups will not aware of the fact that they will receive the medication or placebo. The statistician will also analyze the data with coding so that he will also not aware that which data is related to the control group and which data will be related to the intervention group.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Zahedan University of Medical Sciences

Street address
Zahedan University of Medical Sciences , Dr hesabi sq.

City
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Province
Sistan-va-Balouchestan

Postal code
9816743463

Approval date
2017-06-18, 1396/03/28

Ethics committee reference number
IR.ZAUMS.REC.1396. 19

Health conditions studied

1

Description of health condition studied
Tonsil's inflammation

ICD-10 code
C09.9
ICD-10 code description
Tonsil, unspecified

Primary outcomes

1

Description
agitation
Timepoint
Prior to admission, pain is measured by face scale and children's agitation will measured by the Richmond Agitation Sedation Score. The two cases are also measured after admission and receiving drugs in the PICU, as well as 10, 20, and 30 minutes after extubation of the tube tract. (0: vigilant and calm, 1: restless, 2: disturbed, 3: very disturbed and 4: controversy and fights)
Method of measurement
pain is measured by face scale and children's agitation will measured by the Richmond Agitation Sedation Score

Secondary outcomes

empty

Intervention groups

1

Description
Intervention Group 1:Receiving Dexamethasone and placebo acetaminophen (Dexamethasone At the request of the hospital's drugstore intravenously 0.2 mg / kg in addition to 0.25 mg / kg of syrup with strawberry flavor)
Category
Treatment - Drugs

2

Description
Intervention group2: Receiving Acetaminophen and Dexamethasone placebo (20 mg per kg of acetaminophen syrup At the request of the hospital's drugstore with 0.5 ml / kg of normal saline)
Category
Treatment - Drugs

3

Description
Intervention group3: Receiving Acetaminophen and Dexamethasone (20 mg / kg acetaminophen syrup At the request of the hospital's drugstore with 0.2 mg / kg intravenous dexamethasone At the request of the hospital's drugstore)
Category
Treatment - Drugs

4

Description
Control group: Receiving dexamethasone placebo and acetaminophen placebo (normal saline 0.5 ml / kg plus 0.25 mg / kg of syrup with strawberry flavor)
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Khatam Al-Anbia Hospital in Zahedan City
Full name of responsible person
Aziz Allah Jahantigh
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Khatam al anbia hospital, Jame jam Boulevard
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Sponsors / Funding sources

1

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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
Zahedan 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

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medical student
Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available