

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of rehydration and ketamine on postoperative pain in children undergoing adenotonsillectomy in shahid Mohammadi hospital of Bandar Abbas at 2014

Protocol summary

Summary

Aim of this study: Comparing the effects of fluid administration with intravenous ketamin on postoperative pain after adenotonsillectomy in children. Type of study: Randomized, double blind clinical trial. Population of study: Eighty infants who are candidate for adenotonsillectomy operation in Shahid Mohammadi Hospital Inclusion criteria: age 5 - 8 years; ASA I-II Exclusion criteria: Systemic disease; Metabolic disease; Endocrine disease; mental retardation; failure to thrive; history of allergic disease; tonsilar abscess; hypertension; chronic pain; individuals who are on treatment for chronic pain Method: After informing the parents about the investigation and obtaining consent the infants will be allocated randomly (drawing random cards method) into either group ketamine (K) or fluid therapy (NS). Five minutes before anesthesia induction for group K intravenous ketamine (0.2 mg/kg) and for group NS normal saline (10 cc/kg) will be administered. Induction of anesthesia is provided by fentanyl (2 microgm/kg), lidocaine (1 mg/kg) and sodium thiopental (5 mg/kg) which are followed by tracheal intubation. Anesthesia maintenance will be by oxygen and nitrous oxide (50/50%) with propofol infusion (100 microgram/kg/min). The patients will be evaluated during their recovery by the visual analogue scale (0 - 100 points) at 0, 2, 6, 12 and 24 hours after the end of operation. The level of sedation will be assessed by Ramsey-H scoring system (1-6 points). The data will be collected by a student who is unaware of the type of drug applied during the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015071318091N3**

Registration date: **2016-04-14, 1395/01/26**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-04-14, 1395/01/26

Registrant information

Name

Fekrat Fereydoon

Name of organization / entity

Hormozgan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 76 3334 4009

Email address

fereydoon.fekrat@hums.ac.ir

Recruitment status

Recruitment complete

Funding source

governmental resources of Shahid Mohammadi Hospital, Hormozgan University of Medical Sciences

Expected recruitment start date

2015-07-23, 1394/05/01

Expected recruitment end date

2015-10-23, 1394/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of rehydration and ketamine on

postoperative pain in children undergoing adenotonsillectomy in shahid Mohammadi hospital of Bandar Abbas at 2014

Public title

comparing the effects of fluid therapy and ketamin drug administration on pain after adeniod and tonsilar

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: age 5 - 8 years; ASA I-II Exclusion criteria: Systemic disease; Metabolic disease; Endocrine disease; mental retardation; failure to thrive; history of allergic disease; tonsilar abscess; hypertension; chronic pain; individuals who are on treatment for chronic pain

Age

From **5 years** old to **8 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

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

Deputy for Research, and Medical Ethics Committee of Hormozgan University of Medical Sciences

Street address

Joomhoori Islami Blvd., Shahid Mohammadi Hospital

City

Bandar Abbas

Postal code

7919915519

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

HUMS.REC.1394.63

Health conditions studied

1

Description of health condition studied

Hypertrophy of tonsils with hypertrophy of adenoids disease

ICD-10 code

J35.3

ICD-10 code description

Hypertrophy of tonsils with hypertrophy of adenoids

Primary outcomes

1

Description

to decrease the pain level after tonsilectomy

Timepoint

after the end of tonsilectomy

Method of measurement

Visual Analogue Scale: VAS

Secondary outcomes

1

Description

nausea and vomiting

Timepoint

In recovery at 0, 2, 6, 12, 24 hours after adenotonsilectomy operation

Method of measurement

Descriptive

2

Description

Sedation condition

Timepoint

In recovery at 0, 2, 6, 12, 24 hours after adenotonsilectomy operation

Method of measurement

Ramsey-H score

Intervention groups

1

Description

Five minutes before anesthesia induction for group K intravenous ketamine (0.2 mg/kg) will be administered. Induction of anesthesia is provided by fentanyl (2 microgm/kg), lidocaine (1 mg/kg) and sodium thiopental (5 mg/kg) which are followed by tracheal intubation. Anesthesia maintenance will be by oxygen and nitrous oxide (50/50%) with propofol infusion (100 microgram/kg/min).

Category

Treatment - Drugs

2

Description

Five minutes before anesthesia induction for group NS normal saline (10cc/kg) will be administered. Induction of anesthesia is provided by fentanyl (2 microgm/kg), lidocaine (1 mg/kg) and sodium thiopental (5 mg/kg) which are followed by tracheal intubation. Anesthesia maintenance will be by oxygen and nitrous oxide (50/50%) with propofol infusion (100 microgram/kg/min).

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Mohammadi Hospital

Full name of responsible person

Alireza Abdolazade Baghaee

Street address

Joomhoori Islami Blv., Shahid Mohammadi Hospital

City

Bandar Abbas

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hormozgan University of Medical Sciences

Full name of responsible person

Abdulazim Nejatizadeh

Street address

Joomhoori Islami Blv., Deputy of Research Center,
Shahid Mohammadi Hospital

City

Bandar Abbas

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Hormozgan 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

Contact

Name of organization / entity

Shahid Mohammadi Hospital

Full name of responsible person

Alireza Abdolazade Baghaee

Position

Assistant Professor of Anesthesiology and Intensive care - Fellowship of pain

Other areas of specialty/work

Street address

Joomhoori Islami Blv., Deputy of Research Center,
Shahid Mohammadi Hospital

City

Bandar Abbas

Postal code

7919915519

Phone

+98 76 3334 5009

Fax

Email

bagha_ar@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hormozgan University of Medical Sciences

Full name of responsible person

Alireza Abdolazade Baghaee

Position

Assistant Professor of Anesthesiology and Intensive care - Fellowship of Pain

Other areas of specialty/work

Street address

Joomhoori Islami Blv., Deputy of Research Center,
Shahid Mohammadi Hospital

City

Bandar Abbas

Postal code

Phone

+98 76 3334 5009

Fax

Email

bagha_ar@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Hormozgan University of Medical Sciences

Full name of responsible person

Fereydoon Fekrat

Position

Specialist in Anesthesiology and Intensive care

Other areas of specialty/work

Street address

Joomhoori Islami Blv., Shahid Mohammadi Hospital

City
Bandar Abbas
Postal code
7919915519
Phone
+98 76 3334 5009
Fax
Email
Web page address

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