Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

Comparison the effect of oral mixture of midazolam and ketamin with oral mixture of meperidine and cholral hydrate in agitation and post operative pain in pediatric patients undergoing tonsillectomy

Protocol summary

Summary

In this study we aim to compare the effect of oral mixture of midazolam and ketamine with oral mixture of meperidine and chloral hydrate in calmness of pediatrics during going to operation room, emergence agitation following operation ,severity of post operative pain and also complications like nausea and vomiting will be compared too.64 pediatrics patients who will be candidate and have study's criteria will be allocated by simple randomization in the two 32 pediatrics groups. In the group one pediatrics will received oral mixture of midazolam5 mg/kg with ketamine 5mg/kg 30 min before going to operation and in group two, pediatrics will received oral mixture mepeidine 1.5 mg/kg and chloral hydrate50 mg/kg 30 min before going to operation.Then pediatrics calmness during going to operation, postoperative pain and agitation will be recorded and will be compared. Also, complications such as nausea and vomiting will be recorded and compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015111611662N8**
Registration date: **2015-12-17, 1394/09/26**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-12-17, 1394/09/26

Registrant information

Name

Mohammad Ali Sahmeddini

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice-Chancellery of Research and Technology, Shiraz University Of Medical Sciences .

Expected recruitment start date

2015-10-23, 1394/08/01

Expected recruitment end date

2016-02-20, 1394/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of oral mixture of midazolam and ketamin with oral mixture of meperidine and cholral hydrate in agitation and post operative pain in pediatric patients undergoing tonsillectomy

Public title

Effect of oral mixture of midazolam and ketamin with oral mixture of meperidine and chloral hydrate on calmness and post operative pain in pediatric tonsillectomy surgery.

Purpose

Supportive

Inclusion/Exclusion criteria

64 pediatrics patients who will be candidate for elective

tonsillectomy under general anesthesia will be enrolled in this study. Exclusion criteria are: emergency surgery; history of cardiopulmonary disorders; hypersensitivity to study's drugs; liver disease; kidney disease and history of convulsion.

Age
From **3 years** old to **8 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **64**

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
Shiraz Medica School Research Ethic Committee

Street address
Shiraz Medical School -Zand Blv

City
Shiarz

Postal code
197871345

Approval date
2015-09-23, 1394/07/01

Ethics committee reference number
IR.sums.med.rec.1394.351

Health conditions studied

1

Description of health condition studied
pain following tonsillectomy

ICD-10 code
R07.0

ICD-10 code description
Pain in throat

Primary outcomes

1

Description
post operative pain

Timepoint
Every hour during first 6 hours post operation

Method of measurement
Backer-Wong-faces pain scale

2

Description
postoperative agitation

Timepoint
after awakening in recovery room

Method of measurement
according to this scale: 1.Asleep ;2. Awake but comfort ;3.Agitate ; 4.severly agitate and difficult to calm

3

Description
calmness during going to operatin theater

Timepoint
During seperation from parents and going to operation theater

Method of measurement
according to this scale: 1.Full awake-calm ; 2. crying ; 3. violent movement ; 4. Asleep

Secondary outcomes

1

Description
Nausea and Vomiting

Timepoint
Every one hour during first postoperative 6 hr

Method of measurement
Nausea is defined as urge to vomiting without ejection ofof the contents of the stomach through the mouth, Vomiting is defined asto eject of the contents of the stomach through the mouth, usually in a series of involuntary spasmic movements.

Intervention groups

1

Description
In the group one pediatrics will be received oral mixture midazolam and ketamine mg/kg 30 min before going to operation room.

Category
Treatment - Drugs

2

Description
in the 2nd group pediatrics will be received oral mixture

of meperidine mg/kg and chloral hydrate mg/kg 30 min before operation

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Khalili training and medical center

Full name of responsible person

Mohamma Ali Sahmeddini

Street address

Khalili Avenue

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-Chancellery of Research and Technology

Full name of responsible person

Dr Seyed Basir Hashemi

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Shiraz University Of Medical Sciences

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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

Vice-Chancellery of Research and Technology

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

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Full name of responsible person

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Position

Fellowship Of Organ Transplantation Anesthesia

Other areas of specialty/work

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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