Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The comparison of normal salin pad and 2% lidocaine pad on post-adenotonsillectomy pain

Protocol summary

Summary

The purpose of the study :The comparison of normal salin pad and 2% lidocaine pad on post-adenotonsillectomy pain 20/5000 Study design: Randomized, double-blind, placebo-controlled, single-center, phase II trial The study population : Children ages 7 to 15 years undergoing adenotonsillectomy referred to ENT Clinic of Khatamolanbia Hospital in 1394 A: Inclusion criteria:15-7year-old age are undergoing adenotonsillectomy Exclusion criteria: Known allergy to lidocaine, Analgesic Drug use during the past 24 hours Number of samples : 104 B : There pad soaked in saline and Lidocaine pads in two different groups C : 12,6,2 and 24 hours after surgery D : Increased postoperative analgesia and reduce the need for pain medication after surgery

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016122931656N1**
Registration date: **2017-05-07, 1396/02/17**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-05-07, 1396/02/17

Registrant information

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Recruitment status

Recruitment complete

Funding source

No fee plan

Expected recruitment start date

2015-03-21, 1394/01/01

Expected recruitment end date

2017-08-23, 1396/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of normal salin pad and 2% lidocaine pad on post-adenotonsillectomy pain

Public title

The effect of normal saline soaked pads on tonsillectomy pain

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:15-7year-old age are undergoing adenotonsillectomy؛Children with recurrent tonsillitis؛ chronic tonsilitis؛ Obstructive sleep apnea syndrome؛Tonsillar hypertrophy؛ dysphagia Exclusion criteria: Known allergy to lidocaine؛Renal or hepatic dysfunction؛Analgesic consumption during the last 24 hours؛ Drug abuse (due to its high prevalence in the region)؛ known Favism disease ، Diarrhea؛ dehydrationr ؛ bleeding disorders

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: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
ZAHEDAN University of Medical Sciences
Street address
Zahedan- dr hesabi square
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zahedan
Postal code
9816743463
Approval date
2016-01-17, 1394/10/27
Ethics committee reference number
IR.ZAUMS.REC.1394.357

Health conditions studied

1

Description of health condition studied
chronic tonsilitis
ICD-10 code
J35
ICD-10 code description
Chronic diseases of tonsils and adenoids

Primary outcomes

1

Description
Pain relief
Timepoint
12,6,2 and 24 hours after surgery.
Method of measurement
asked pain scale

Secondary outcomes

1

Description
Reduce the need for painkillers
Timepoint
6 hours
Method of measurement
pre-arranged questionnaire

Intervention groups

1

Description
Immediately after adenotonsillectomy and extubation pad soaked lidocaine 2% in the intervention group received.All patients remained in hospital for 24 hours after the operation .Postoperative pain using the VAS (visual analog scale) 12,6,2 and 24 hours after surgery were examined.
Category
Treatment - Drugs

2

Description
As before, but with this difference that the control group received normal saline0/9% soaked pad
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Khatam Alnbya hospital
Full name of responsible person
Dr Gholam Ali Dashti
Street address
Khatamol Anbia Hospital ، Khatam Square ، Zahedan
City
Zahedan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Deputy of research and technology, Zahedan University of Medical Science
Full name of responsible person
Dr Refigh Dost
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Zahedan ، Hesabi Square

City
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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
Deputy of research and technology, Zahedan University of Medical Science
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

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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