

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jun 2026

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

Protocol summary

Summary

The purpose of the study :The comparison of normal saline 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

Name

Matin Edizadeh

Name of organization / entity

Zahedan University of Medical Sciences

Country

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Phone

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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 saline 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 tonsillitis: 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: dehydration: 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

City

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 tonsillitis

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

Street address

Zahedan , Hesabi Square

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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

Contact

Name of organization / entity
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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