Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Aug 2026

Evaluation of the effect of local injection of Lidocain on post-tansilectomy pain in children aged 5 -12 years old

Protocol summary

Study aim
Determining the effect of local Injection of Lidocaine on reducing pain after tansillectomy in children

Design
Clinical trial, randomized, parallel group design of 134 patients, triple blind

Settings and conduct
The present study is a Triple-Blind clinical trial that will be done at Persian Gulf Martyr's Hospital, Bushehr, on 134 children aged 5 to 12 years old need tonsillectomy. For random allocation of patients, the surgeon uses a double block to divide the patients into two groups of intervention (Lidocaine recipients) and control (Normal saline recipients). the patient, person evaluating pain and data analyzer will get full blindness on this study and only the surgeon will be fully informed.The Children's Hospital of Eastern Ontario Pain Scale, On this scale, 6 components, which include: crying, facial, child verbal, torso, touch and legs, are evaluated. During evaluation In each part there will be given 0 or 1+ or 2+ points in the various modes, except screaming mode in the cry section that has 3+ points. More points indicate more pain and discomfort. .

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1.Age between 5-12 years, 2.Chronic tonsillitis or recurrent tonsillitis, 3.Severe tonsil hypertrophy causing mechanical obstruction Exclusion criteria: 1.Coagulation disorder, 2.Cardiovascular patients, 3.Disagreement of parents

Intervention groups
In the intervention group: for patients before tansillectomy operation using lidocaine ampoule of 20 mg/ml from Darou Pakhsh company, will be injected at the dose of 1 mg/kg in the tonsillar bed. Lidocaine injection following general anesthesia is performed once by the surgeon. In the control group: before tansillectomy operation, 2 cc normal saline will be injected as a placebo in the tonsillar bed.

Main outcome variables
Evaluation of pain after tonsillectomy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180825040859N1**
Registration date: **2019-01-16, 1397/10/26**
Registration timing: **prospective**

Last update: **2019-01-16, 1397/10/26**
Update count: **0**

Registration date
2019-01-16, 1397/10/26

Registrant information

Name
ali mosaddegh

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-01-30, 1397/11/10

Expected recruitment end date
2019-06-20, 1398/03/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Evaluation of the effect of local injection of Lidocain on post-tansilectomy pain in children aged 5 -12 years old

Public title
Evaluation of the effect of localized Lidocaine Injection on post-tansilectomy pain

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age between 5-12 year's old Chronic tonsillitis or recurrent tonsillitis Peritonsillar abscess Tonsillogenic septicemia Focal symptoms following tonsillitis Severe tonsil hypertrophy causing mechanical obstruction Suspicious to tonsil tumor Resistant carriers of diphtheria bacilli Bad and resistant mouth odor due to the high production of tonsillar plaques Tuberculous lymphadenitis, in which the tonsils are possible entry point

Exclusion criteria:
Metabolic disorders Coagulopathy Mental retardation Developmental dysfunction Drug allergy Psychotic disorders Chronic pain and those who received analgesic Heart patients Disagreement of the parents with their child's participation in the study

Age
From **5 years** old to **12 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **134**

Randomization (investigator's opinion)
Randomized

Randomization description
Among the patients referring to the elective tansillectomy, the population of the sample was selected as simple sampling based on the satisfaction of the company in the study. For random allocation, the participants were divided into two groups of intervention (lidocaine receptor) and control group (normal saline recipients) using four balanced blocks. Random sequence generation is done using Excel software and the size of all blocks is equal. To blind patients after describing the goals of the study and obtain written consent for participation in the study, participants are divided into intervention recipient groups and control groups without any knowledge of the patient of the type of intervention by block method (by assigning different codes). After performing the intervention by the researcher, to assess the severity of pain in patients, the outcome evaluator was not aware of the type of intervention performed and evaluated the patients with the assigned codes. When analyzing data, the data analyzer does not know the partitioning of the groups and the codes assigned to them, and the comparisons are performed under two unspecified groups.

Blinding (investigator's opinion)
Triple blinded

Blinding description
In this study, only the surgeon (project executive) knew the type of intervention and patients, the person assessing the severity of pain and the person analyzing the information, are not aware of the type of intervention group or control group. To blind patients after describing the goals of the study and obtain written consent for participation in the study, participants are divided into intervention recipient groups and control groups without any knowledge of the patient of the type of intervention by block method (by assigning different codes). After performing the intervention by the researcher, to assess the severity of pain in patients, the outcome evaluator was not aware of the type of intervention performed and evaluated the patients with the assigned codes. When analyzing data, the data analyzer does not know the partitioning of the groups and the codes assigned to them, and the comparisons are performed under two unspecified groups.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

Street address
Bushehr University of Medical Sciences, Salman Farsi Ave, Rishehr, Bushehr

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Boushehr

Postal code
7517933755

Approval date
2018-08-21, 1397/05/30

Ethics committee reference number
IR.BPUMS.REC.1397.049

Health conditions studied

1

Description of health condition studied

Pain control after tonsillectomy

ICD-10 code

J35.1

ICD-10 code description

Hypertrophy of tonsils

Primary outcomes

1

Description

Post tonsillectomy pain based on Children's Hospital of Eastern Ontario Pain Scale

Timepoint

In the minutes 15, 30, 60, 120, 240, 360 after tonsillectomy

Method of measurement

Children's Hospital of Eastern Ontario Pain Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: before tonsillectomy, once using lidocaine ampoule of 20 mg/ml from Darou Pakhsh company, will be injected at the dose of 1 mg/kg in the tonsillar bed.

Category

Treatment - Drugs

2

Description

Control group: Before tansillectomy , 2 cc normal saline will be injected as a placebo in the tonsillar bed.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Persian Gulf Martyr’s Hospital, Bushehr

Full name of responsible person

Ali Mosaddegh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Boushehr 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

Contact

Name of organization / entity

Boushehr University of Medical Sciences

Full name of responsible person

Ali Mosaddegh

Position

Medical student

Latest degree

A Level or less

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Yes, the title of the study and how the study is carried out will be published in the form of medical ethics once the results of the study are published
When the data will become available and for how long
Yes, the data will become available 3 months after the results are printed
To whom data/document is available
Yes, after the study is completed, data will be available for academic and research institutes
Under which criteria data/document could be used
After the completion of the project, it will be specified
From where data/document is obtainable
Yes, after publishing the results, you can receive documents or data by e-mail mosaddegh.med@gmail.com or phone number 00989178744511 (Ali Mossadegh).
What processes are involved for a request to access data/document
The release plan is still unknown
Comments