

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Comparison of the effect of normal saline cold grass with honey and normal saline cold on the pain of children's tonsillectomy/adenotonsillectomy

Protocol summary

Study aim

1.Comparison of the effect of normal serum glucose stabilization of cold saline after surgery on the pain of the site of operation Tonsillectomy / Adenotonsillectomy by routine method 2.Comparison of the effect of normalizing serum saline with honey after surgery on pain in the site of operation Tonsillectomy / Adenotonsillectomy by routine method 3.Comparison of the effect of normal serum saline normalization with honey with normal cold saline after surgery on pain in the site of operation Tonsillectomy / Adenotonsillectomy

Design

Clinical trials with control group, community based and pragmatic, with parallel groups, double blind, randomized

Settings and conduct

Hospital of Bojnourd University of Medical Sciences. The research population of patients aged between 5-14 years of age who are candidates for Tonsillectomy / Admontonsillectomy who are ASA (class of Association of American Anesthesiology Association) in grade one and two after receiving written consent from the parents of the patient, samples The target group will consist of 35 people in each group. All patients will be operated by a surgeon and undergo general anesthesia.

Participants/Inclusion and exclusion criteria

Criteria for entering the study: Tonsillectomy / Elective adenotonsillectomy ASA class one and two Aged 5-14 years old Obtaining written consent from the patient Exit for criteria the study: Need to re-intubate Bleeding and needing re-operation Failure to intubate the chip Bleeding disorders Systemic diseases like diabetes

Intervention groups

Normal saline (NC) groups, normal saline group with honey (NH) and normal saline (temperature) (control group) (N)

Main outcome variables

The amount of pain, weight, hemorrhage, child's relaxation before and after surgery, sleep before and after the child, nausea and vomiting, breathing situation, throat itching

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190113042346N1**

Registration date: **2019-02-10, 1397/11/21**

Registration timing: **registered_while_recruiting**

Last update: **2019-02-10, 1397/11/21**

Update count: **0**

Registration date

2019-02-10, 1397/11/21

Registrant information

Name

hosnieh raufiyan

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 51 3657 6830

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-22, 1397/09/01

Expected recruitment end date

2019-02-19, 1397/11/30

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of normal saline cold grass with honey and normal saline cold on the pain of children`s tonsillectomy/adenotonsillectomy

Public title
Comparison of the effect of normal saline cold grass with honey and normal saline cold on the pain of children`s tonsillectomy/adenotonsillectomy

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Tonsillectomy / Elective adenotonsillectomy ASA class one and two Aged 5-14 years old Obtaining written consent from the patient
Exclusion criteria:
Need to re-intubate Bleeding and needing re-operation Failure to intubate the chip Bleeding disorders Systemic diseases like diabetes

Age
From **5 years** old to **14 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **105**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be referred to on a regular basis. Patient allocation will be done in groups of this study using Block Randomization. In this way, by determining the blocks and randomly choosing blocks, the patient number received by the group of three The frequency is determined and then the number of patients in the group according to the requirements of the code is specified and according to the codes, gradually, by referring the patients to the intervention is done. To determine the normal saline (NC) intervention groups, the normal saline group with honey (NH) and normal saline is also characterized by temperature (control group) (N). And patients are given four-digit code

Blinding (investigator's opinion)
Double blinded

Blinding description
To blind people, patients who do not wake up will not notice that they are in the group's custody, and the pain assessor will not be informed about which group the patient is in.

Placebo

Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Deputy of Research and Technology of Mazandaran University of Medical Sciences

Street address

Sari, Three streams Joybar, Beginning of Valiasr highway, central headquarters of Mazandaran University of Medical Sciences and Health Services

City

Sari

Province

Mazandaran

Postal code

48157-33971

Approval date

2018-12-05, 1397/09/14

Ethics committee reference number

IR.MAZUMS.REC.1397.165

Health conditions studied

1

Description of health condition studied

Post-operative pain Tonsillectomy / Adenotonsillectomy

ICD-10 code

R07.0

ICD-10 code description

Pain in throat

Primary outcomes

1

Description

Postoperative pain Tonsillectomy / Adenotonsillectomy

Timepoint

When clearance is recovered, and at intervals every 6 hours on the first day, the end of the first day, the end of the second day

Method of measurement

For the assessment of pain, Wang Baker's scale for children will be used for children.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention groupe: First intervention: In the normal group of saline with honey (NH) at the end of the operation, the pharyngeal cavity and around the tonsils at the end of the operation with normal saline 0.9%, the temperature with the room washed and cleaned and then suctioned, and after the operation, the patient's pain It is recorded in the recovery at the time of discharge and every 6 hours for two days gargle the normal solution of saline 0.9% to 100 cc at a concentration of 10/10 with mixed honey (100 ml of honey mixed per liter of normal saline) The patient is given and after each time gargle the pain is recorded and the pain will be recorded on the first and second day after the sharp operation. Second intervention: In the normal saline group, 4 ° C (NC) was washed and cleaned at the end of the oral cavity and around the tonsil with normal saline 0.9% and then suctioned and recorded in the recovery procedure at the time of discharge. A normal saline solution was placed in the refrigerator and using the thermometer in the refrigerator, the solution temperature would be used when it reached 4 ° C, and every 6 hours the normal solution of saline was 0.9% cold at 4 ° C at 100 cc by the gargole patient And the amount of pain after gargoying each time and on the first and second day after the operation will be recorded.

Category

Treatment - Surgery

2

Description

Control group: In the control group (N), the routine routine washing of the pharyngeal cavity and around the tonsils at the end of the surgery will be done, and the pain will be recorded in recovery and every 6 hours on the first and second day after the operation. And there will be no intervention

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hassan Hospital

Full name of responsible person

Reza Ghaffari

Street address

Bojnourd - Orcan road, above wheat silo, Imam Hasan educational, research and therapeutic center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Said Majidi

Street address

Sari, Imam Square, Three Way Joybar, Beginning of Vali-e-Asr Highway, Mazandaran 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

Sari 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

Mazandaran University of Medical Sciences

Full name of responsible person

Hosnieh Raufiyan

Position

Student

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

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Position

Assistant Professor, collegian

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

Hosnieh Raufiyan

Position

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Latest degree

Master

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not 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

Undecided - It is not yet known if there will be 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

We will record the data obtained after the illness.

When the data will become available and for how long

Get started 6 months after printing results محققین

To whom data/document is available

Researchers and researchers at academic and academic institutions

Under which criteria data/document could be used

Using the source and the researchers' satisfaction, this study is applicable

From where data/document is obtainable

Can contact Hosnieh Raufiyan at h.raufyian@gmail.com

What processes are involved for a request to access data/document

Upon receipt of a request for access to the document, it will be delivered to the maximum of up to two months

Comments