# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 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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**Email address**

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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 Tansillectomy / 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**
Intervetion 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 gargoyle 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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Bojnord

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North Khorasan

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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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msaeidi@mazums.ac.ir

**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

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Assistant Professor, collegian

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## Person responsible for updating data

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**Position**
Student

**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 resultsمحققین

**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**