Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of topical ketamine injection at the site of tonsillectomy in reducing post-tonsillectomy pain in people under 18 years of age in Booalisina hospital from 2023 to 2024

Protocol summary

Study aim

The effect of topical ketamine injection at the site of tonsillectomy in reducing post-tonsillectomy pain in people under 18 years of age in Booalisina hospital from 2023 to 2024

Design

Clinical trial, with parallel groups, randomized, double-blind, phase 2-3 on 60 patients, Random allocation software will be used for randomization.

Settings and conduct

The total sample in each group is 30 people, which will be performed on patients under 18 years of age who are candidates for tonsillectomy, hospitalized in Bo Ali Sina Hospital, Sari during the years 2023 to 2024. /kg of ketamine locally and the second group is considered as a control group that does not receive any medicine.In case of pain control with topical ketamine and the need for painkillers Intravenous acetaminophen is used at a dose of 12 mg/kg every 4 hours with a maximum dose of 75 mg within 24 hours. Post-operative pain (during recovery, 6 and 12 hours after the operation) using The eye analog criterion is asked to the patient by a trained nurse during recovery, hospitalization and under patient observation in the hospital.

Participants/Inclusion and exclusion criteria

A person's willingness to participate in obtaining informed consent. Chronic tonsillitis characterized by 7 or more episodes of sore throat per year for two consecutive years or 3 or more episodes of sore throat per year for three consecutive years.Occurrence of obstructive symptoms related to tonsil hypertrophy.Patients of both sexes under 18 years of age.

Intervention groups

The first group is the intervention group, which receives 1mg/kg of ketamine topically.The control group does not receive medication and the patient's pain is treated with intravenous acetaminophen at a dose of 12 mg/kg every 4 hours with a maximum dose of 75 mg within 24 hours after surgery

Main outcome variables

Postoperative pain measurement time; the amount of pain after the operation.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231216060427N1**
Registration date: **2024-01-09, 1402/10/19**
Registration timing: **registered_while_recruiting**

Last update: **2024-01-09, 1402/10/19**
Update count: **0**

Registration date

2024-01-09, 1402/10/19

Registrant information

Name

Mahsa Heidari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4723 5778

Email address

drmahsaheidari@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-22, 1402/10/01

Expected recruitment end date

2024-05-21, 1403/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of topical ketamine injection at the site of tonsillectomy in reducing post-tonsillectomy pain in people under 18 years of age in Booalisina hospital from 2023 to 2024

Public title

The effect of topical ketamine injection at the site of tonsillectomy in reducing post-tonsillectomy pain in people under 18 years of age in Booalisina hospital from 2023 to 2024

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

A person's willingness to participate in obtaining informed consent Chronic tonsillitis characterized by 7 or more episodes of sore throat per year for two consecutive years or 3 or more episodes of sore throat per year for three consecutive years. Occurrence of obstructive symptoms related to tonsil hypertrophy Patients of both sexes under 18 years of age

Exclusion criteria:

The patient's unwillingness to continue to cooperate in the study History of taking painkillers Patients with a history of bleeding disorders Hemoglobin less than 10 g/dL History of rheumatological diseases Patients who have difficulty expressing pain

Age

From **5 years** old to **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

To control the intervening variables and also to balance the groups in terms of number, a random block method was used based on the order of patients' entry, that is, from the first four patients, the data of 4 patients were allocated to two groups using random allocate software. Then this allocation of four continued until the samples were completed based on the sample size.

Blinding (investigator's opinion)

Double blinded

Blinding description

After selecting the samples, none of the sampled people will know about randomization and the process of allocation to groups. Patients are included in the study in the order of table numbers. In the intervention group, at the beginning of the surgery, ketamine at a dose of 1mg/kg will be injected locally in the tonsillectomy area for all patients by the attending physician in the operating room. And the control group does not receive medicine. In the case of blinding, the patient and the nurse responsible for evaluating the pain score do not know whether the medicine has been injected into the patient or not. The student is an observer in the operating room.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Mazandaran University of Medical Sciences

Street address

Mazandaran University of Medical Sciences, at the begining of Valiasr Highway, Joibar three ways, imam Square,Sari, Mazndaran Province

City

Sari

Province

Mazandaran

Postal code

4815733971

Approval date

2023-12-13, 1402/09/22

Ethics committee reference number

IR.MAZUMS.REC.1402.512

Health conditions studied

1

Description of health condition studied

Tonsillitis

ICD-10 code

J35

ICD-10 code description

Chronic diseases of tonsils and adenoids

Primary outcomes

1

Description

The outcome of the patient's pain intensity after the

operation based on the eye analog criterion

Timepoint

Pain intensity during recovery, 6 and 12 hours after surgery

Method of measurement

These results are measured by the evaluator, who is a trained nurse, who does not know about the allocation of the study subjects to each of the two allocation groups and the drugs used. Pain intensity is recorded during recovery 6 and 12 hours after the operation. The instrument for measuring this variable is based on the visual analog scale, and the face part of the visual analog scale will be used to measure the pain of patients aged 5 to 7 years, and the numerical part will be used to measure the pain of patients over 7 years old, and the help of the patient's parents will be taken to measure the pain.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, at the beginning of the surgery, ketamine at a dose of 1mg/kg will be injected locally in the tonsillectomy area for all patients by the attending physician in the operating room.

Category

Treatment - Drugs

2

Description

Control group: The control group does not receive medication and the patient's pain is treated with intravenous acetaminophen at a dose of 12 mg/kg every 4 hours or 15 mg/kg every 6 hours with a maximum dose of 75 mg within 24 hours after the operation.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sari Buali Sina Hospita

Full name of responsible person

Mahsa Heidari

Street address

Buali Sina Hospital, First of Ghaemshahr road. Sari

City

Sari

Province

Mazandaran

Postal code

۴۸۱۵۸۳۸۴۷۷

Phone

+98 11 3304 4001

Email

Publicrel@mazums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Pedram Ebrahimnejad

Street address

Headquarters of Mazandaran University of Medical Sciences. At the beginning of Valiasr Highway.Sari

City

Sari

Province

Mazandaran

Postal code

4414733971

Phone

+98 11 3303 4001

Email

Publicrel@mazums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Mazandaran 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

Mahsa Heidari

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Ear, Nose, and Throat

Street address

Headquarters of Mazandaran University of Medical

Sciences. At the beginning of Valiasr Highway.Sari
City
Sari
Province
Mazandaran
Postal code
4815733971
Phone
+98 11 3304 4001
Email
drMahsaheidari@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Mahsa Heidari
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Ear, Nose, and Throat
Street address
Headquarters of Mazandaran University of Medical Sciences. At the beginning of Valiasr Highway.Sari
City
Sari
Province
Mazandaran
Postal code
4815733971
Phone
+98 11 3304 4001
Email
drMahsaheidari@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Mahsa Heidari
Position
Associate Professor
Latest degree
Specialist
Other areas of specialty/work
Ear, Nose, and Throat
Street address
Headquarters of Mazandaran University of Medical Sciences. At the beginning of Valiasr Highway.Sari
City
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Province
Mazandaran
Postal code
4815733971
Phone
+98 11 3304 4001
Email
drMahsaheidari@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available