

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Evaluation of the effect of topical injection of "morphine, triamcinolone and lidocaine" in comparison with "lidocaine" on pain intensity after mastoidectomy-tympanoplasty

Protocol summary

Study aim

Determining and comparing the effect of topical injection of "morphine, triamcinolone and lidocaine" and "lidocaine" on pain intensity after mastoidectomy-tympanoplasty

Design

A randomized, double-blinding clinical trial, with the parallel groups, Phase 3 on 68 patients

Settings and conduct

In this randomized double-blind clinical trial study, 68 eligible patients referred to Alzahra and Kashani hospitals in Isfahan will be included in the study and will be randomly divided into two groups. Before anesthesia, the first group will receive a topical injection of a combination of morphine, triamcinolone, and lidocaine, and the second group will receive a topical injection of lidocaine. Then the patients' pain score and hemodynamic parameters will be evaluated and compared between the two groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria include 15 to 65 years of age, indication for mastoidectomy-tympanoplasty, and consent to participate in the study. Exclusion criteria include having a history of drug and alcohol addiction, having a history of seizures and mental health problems, having kidney disease, and dying.

Intervention groups

Intervention group: In this group, 0.15 mg/kg morphine (Daru Pakhsh Company) and 10 mg triamcinolone (Germany Hexal Company) to 100 mg lidocaine 2% (Aburaihan Tehran) and epinephrine with a concentration of 1 to 100,000 (Daru Pakhsh Company) are added and injected topically by the surgeon at the surgical incision site before surgery. Control group: In this group, according to the usual method, 0.15 mg/kg morphine (Daru Pakhsh Company) is injected intravenously before surgery. Then, 100 mg of lidocaine 2% (Aburaihan

Company) and epinephrine with a concentration of 1 to 100,000 (Daru Pakhsh Company) are injected topically at the surgical incision site before surgery.

Main outcome variables

Pain; Hemodynamic parameter

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200825048515N39**

Registration date: **2021-09-20, 1400/06/29**

Registration timing: **prospective**

Last update: **2021-09-20, 1400/06/29**

Update count: **0**

Registration date

2021-09-20, 1400/06/29

Registrant information

Name

Asieh Maghami Mehr

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2021-12-21, 1400/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of topical injection of "morphine, triamcinolone and lidocaine" in comparison with "lidocaine" on pain intensity after mastoidectomy-tympanoplasty

Public title

The effect of topical injection of "morphine, triamcinolone and lidocaine" and "lidocaine alone" on postoperative pain intensity

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 15 to 65 years Indicated for mastoidectomy-tympanoplasty Satisfaction to participate in the study

Exclusion criteria:

Having a history of drug and alcohol addiction Having a history of seizures and mental health problems Having kidney disease Death of the patient

AgeFrom **15 years** old to **65 years** old**Gender**

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample sizeTarget sample size: **68****Randomization (investigator's opinion)**

Randomized

Randomization description

In this study, 68 eligible patients will be randomly selected. Then random numbers are created by computer software "Random Allocation". We randomly divide these numbers into two parts. Each number is written on paper and placed in an envelope. Then each patient is asked to choose an envelope from among the envelopes. According to the selected envelope, the patient will be assigned to one of the two groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

To blind the study, the drugs will be prepared by the operating room technician before the intervention. In terms of the amount of the drug, all drugs will be reached the same volume using distilled water. These syringes will be coded and placed in the operating room and delivered daily to the researcher, who will prescribe them without knowing the type of medication. Also, the

patient, the person recording the clinical and basic information of the patients as well as the statistical analyst will not be aware of the type of intervention.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Isfahan University of Medical Sciences

Street address

Street address Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq

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Province

Isfahan

Postal code

8179964167

Approval date

2021-04-25, 1400/02/05

Ethics committee reference number

IR.MUI.MED.REC.1400.064

Health conditions studied**1****Description of health condition studied**

Mastoidectomy-tympanoplasty Surgery

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Pain score

Timepoint

Immediately upon entering the recovery and at 2, 8, 12 and 24 hours after surgery

Method of measurement

Visual Analogue Scale

Secondary outcomes**1****Description**

Systolic blood pressure
Timepoint
Before induction of anesthesia, immediately after induction of anesthesia and every ten minutes during surgery until the end of surgery
Method of measurement
Monitoring device

2

Description
Diastolic blood pressure

Timepoint
Before induction of anesthesia, immediately after induction of anesthesia and every ten minutes during surgery until the end of surgery

Method of measurement
Monitoring device

Intervention groups

1

Description
Intervention group: In this group, 0.15 mg/kg morphine (Daru Paksh Company) and 10 mg triamcinolone (Germany Hexal Company) to 100 mg lidocaine 2% (Aburaihan Tehran) and epinephrine with a concentration of 1 to 100,000 (Daru Paksh Company) is added and injected topically by the surgeon at the surgical incision site before surgery.

Category
Treatment - Drugs

2

Description
Control group: In this group, according to the usual method, 0.15 mg/kg morphine (Daru Paksh Company) is injected intravenously before surgery. Then, 100 mg of lidocaine 2% (Aburaihan Company) and epinephrine with a concentration of 1 to 100,000 (Daru Paksh Company) are injected topically at the surgical incision site before surgery.

Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra Hospital
Full name of responsible person
Reihanak Talakoub
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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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dean@med.mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Isfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Reihanak Talakoub
Position
Associate Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology

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Associate Professor

Latest degree

Specialist

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Person responsible for updating data**Contact****Name of organization / entity**

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Non-faculty specialist physician

Latest degree

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available