Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 topicaly 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)

Phone

+98 31 0000 0000

Email address

asimaghami@yahoo.com

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
Age
From **15 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target 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
City
Isfahan
Province
Isfehan
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 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) 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 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.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital

Full name of responsible person

Reihanak Talakoub

Street address

Anesthesiology Department, Al-Zahra Hospita, Sefeh Blvd., Tohid Street

City

Isfahan

Province

Isfehan

Postal code

8174675731

Phone

+98 31 3620 2020

Email

Talakoub@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjooy Javanmard

Street address

Vice Chancellor for Research, School of Medicine, Hezar Jarib Street, Isfahan.

City

Isfahan

Province

Isfehan

Postal code

8174673461

Phone

+98 31 3668 8597

Email

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

Street address
Anesthesiology Department, Al-Zahra Hospita, Sefeh Blvd., Tohid Street
City
Isahan
Province
Isfehan
Postal code
8174675731
Phone
+98 31 3620 2020
Email
Talakoub@med.mui.ac.ir

Person responsible for scientific 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
Street address
Anesthesiology Department, Al-Zahra Hospita, Sefeh Blvd., Tohid Street
City
Isahan
Province
Isfehan
Postal code
8174675731
Phone
+98 31 3620 2020
Email
Talakoub@med.mui.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Hoda alsadat Roohani
Position
Non-faculty specialist physician
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Anesthesiology Department, Al-Zahra Hospita, Sefeh Blvd., Tohid Street
City
Isahan
Province
Isfehan
Postal code
8174675731
Phone
+98 31 3620 2020
Email
Hoda.Roohani@yahoo.com

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