

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Preventive effect of adding morphine to topical lidocaine in the case group compared with normal saline increase to topical lidocaine and intravenous morphine in the control group on pain intensity after mastoidectomy-tympanoplasty

Protocol summary

Study aim

The study of the preventive effect of adding Morphine to local lidocaine 2% on the pain intensity after mastoidectomy-tympanoplasty surgery and its comparison with control group

Design

80 patients were divided into two groups of 40 patients (lidocaine with morphine) and control (lidocaine) in a randomized block. A parallel and single-phase study was conducted to evaluate the preventive effect of adding morphine to lidocaine on patients undergoing elective mastoidectomy-tympanoplasty.

Settings and conduct

Patient's history was recorded by the researcher through a pre-surgical check-up checklist in the recovery department of Isfahan's Al-Zahra Hospital. The patient did not know the therapeutic content of the pain reduction method. Data was also provided to the data analyst without any personal information or type of therapy group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients aged between 15-65 years old and have no underlying disease or at least an underlying controlled disease. Patients undergoing mastoidectomy-tympanoplasty surgery have no history of drug and alcohol addiction, seizure and mental problems, and kidney disease. Exclusion criteria: Prolonged operation for more than 2.5 hours, the possibility of a patient's phallopathy until the end of the intervention for various reasons such as death.

Intervention groups

In the intervention group, 0.15 mg / kg of morphine was added to 100 mg of lidocaine 2% and epinephrine 1: 200000, and in the control group, the same volume of normal saline was added to lidocaine and epinephrine and injected at the surgical site and the patient was 0.15

milligram per kilogram of morphine are given intravenously.

Main outcome variables

Severity of postoperative pain and hemodynamic changes during and after mastoidectomy-tympanoplasty

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171230038142N3**

Registration date: **2018-12-04, 1397/09/13**

Registration timing: **retrospective**

Last update: **2018-12-04, 1397/09/13**

Update count: **0**

Registration date

2018-12-04, 1397/09/13

Registrant information

Name

Khosro Tavakol

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 9134

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tavakol@nm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-05-22, 1396/03/01

Expected recruitment end date

2018-02-19, 1396/11/30

Actual recruitment start date

2016-05-21, 1395/03/01

Actual recruitment end date

2018-03-11, 1396/12/20

Trial completion date

2018-03-11, 1396/12/20

Scientific title

Preventive effect of adding morphine to topical lidocaine in the case group compared with normal saline increase to topical lidocaine and intravenous morphine in the control group on pain intensity after mastoidectomy-tympanoplasty

Public title

The study of the preventive effect of adding Morphine to local lidocaine2% on the pain intensity after mastoidectomy-tympanoplasty surgery

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Age of 15-65 years No underlying disease or at least have controled underlying disease. Patients undergoing mastoidectomy-tympanoplasty surgery

Exclusion criteria:

No history of drug and alcohol addiction No history of seizures and mental problems Lack of kidney disease

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

Both

Phase

3

Groups that have been masked

- Participant
- Data analyser

Sample sizeTarget sample size: **80**Actual sample size reached: **80****Randomization (investigator's opinion)**

Randomized

Randomization description

Patients were divided into intervention and control groups using block randomisation and 40 patients were assigned to each group. Thus, considering two blocks of forty, 20 patients were treated with lidocaine and 20 patients using lidocaine and morphine.

Blinding (investigator's opinion)

Double blinded

Blinding description

After assigning patients to two groups of intervention and control, the patient's history was recorded by the researcher through the pre-surgery checklist in recovery and in the department. The patient did not know the therapeutic content of the pain reduction method. Data was also provided to the data analyst without any personal information or type of therapy group.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences & Health Services, Hezarjarib Ave.

City

Esfahan

Province

Isfahan

Postal code

81747-73461

Approval date

2017-05-21, 1396/02/31

Ethics committee reference number

IR.MUI.REC.1396.3.077

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

Severity of pain after mastoidectomy-tympanoplasty

ICD-10 code

Z09.0

ICD-10 code description

Follow-up examination after surgery for other conditions

Primary outcomes**1****Description**

pain intensity

Timepoint

Measurement of pain intensity at pre-induction, after induction and during surgery was measured.

Method of measurement

Using the pain scale and the patient's questioning

Secondary outcomes

empty

Intervention groups**1****Description**

The intervention group was treated with topical lidocaine 2% and epinephrine by adding 15.0 mg / kg of morphine to one hundred milligrams.

Category

Prevention

2

Description

Control group: One hundred mg of local lidocaine 2% and epinephrine were surgically treated with 0.15 mg / kg of intravenous morphine. This was followed by surgery with localized lidocaine and intravenous morphine with normal saline increase.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital in Isfahan

Full name of responsible person

Khalili Gholam Reza

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Al-Zahra Hospital, Sofah Boulevard.

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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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Grant name

Deputy of Research of Isfahan University of Medical Sciences

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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

Khalili Gholam Reza

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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

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

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Yes - There is a plan to make this available

Analytic Code

Yes - There is 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

Data can be shared after the patient is not identified and after obtaining permission from the research vice president and after publication of the article.

When the data will become available and for how long

Two years after printing, it is possible to access the data with the permission of the research vice president.

To whom data/document is available

All researchers in the medical group, especially the anesthetic group.

Under which criteria data/document could be used

To extend the results or compare the results of another study with the present study, with the consent of the researcher and the Isfahan University of Medical Sciences, the results and documentation can be used.

From where data/document is obtainable

To receive the documentation after obtaining permission from the Research and Student Vice-Dean of the Isfahan University of Medical Sciences, e-mail khalili@med.mui.ac.ir.

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

After obtaining permission from the Research and Student Vice-Chancellor of the Isfahan University of Medical Sciences, please send an e-mail to khalili@med.mui.ac.ir, clearly.

Comments