

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Investigate the effectiveness of adding Methadone to local Lidocaine in postoperative pain of Mastoidectomy-tympanoplasty surgery in comparison with control group

Protocol summary

Study aim

As there was no previous study to investigate the effectiveness of adding methadone to local lidocaine in reducing post operative pain of Mastoidectomy-tympanoplasty, we decided to do this study.

Design

Parallel group trial, double blind, not randomized

Settings and conduct

74 patients were chosen by not-randomized sampling. Each patient was given a number between 1-74 randomly and the patients with odd number were put into case group and the patients with even number were put into control group. The blinding method: the patients had no idea about the drug. Also the drugs in the syringes were the same. Also the researcher was not aware of the codes on the syringes.

Participants/Inclusion and exclusion criteria

Candidates for Mastoidectomy-tympanoplasty, Age between 18-65, ASA 1 AND 2, No history of seizure or psychologic problems or kidney disorders, No history of chronic using NSAID, opioid, TCA, alcohol.

Intervention groups

Case group: Receiving Methadone and local Lidocaine
Control group: Receiving normal saline and local Lidocaine

Main outcome variables

Reducing post operative pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100422003771N2**

Registration date: **2019-08-20, 1398/05/29**

Registration timing: **retrospective**

Last update: **2019-08-20, 1398/05/29**

Update count: **0**

Registration date

2019-08-20, 1398/05/29

Registrant information

Name

Gholamreza Khalili

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 1233 0066

Email address

khalili@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-23, 1397/06/01

Expected recruitment end date

2019-03-03, 1397/12/12

Actual recruitment start date

2018-10-04, 1397/07/12

Actual recruitment end date

2019-03-11, 1397/12/20

Trial completion date

2019-03-11, 1397/12/20

Scientific title

Investigate the effectiveness of adding Methadone to local Lidocaine in postoperative pain of Mastoidectomy-tympanoplasty surgery in comparison with control group

Public title

The effectiveness of Methadone on postoperative pain of Mastoidectomy-tympanoplasty surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Candidate for Mastoidectomy-tympanoplasty surgery
No history of seizure disorder
No psychologic problems
No nephrologic disorder
No history of chronic using NSAID, opioid, TCA and alcohol
Age between 18 to 65 years old
ASA one and two

Exclusion criteria:

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **74**

Actual sample size reached: **74**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

This was a double blind study. The patients had no idea about the used drug. Also the Methadone in the syringes was the same and also the researcher did not know about the codes on the syringes.

Placebo

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

Hezar jarib Ave. Isfahan University of Medical Sciences

City

Isfahan

Province

Isfahan

Postal code

۷۳۴۶۱-۸۱۷۴۶

Approval date

2018-10-03, 1397/07/11

Ethics committee reference number

IR.MUI.MED.REC.1397.061

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 in Visual Analogue Scale

Timepoint

Measuring the pain score when entering the recovery at 0,2,4,6,12 and 24 hour after surgery.

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Case group: 10 mg Methadone was added to 100 mg Lidocaine 2% and epinephrine 1/200000 and was injected in site of surgery before the start of operation .
Control group : The same volume of normal saline was added to 100 mg Lidocaine 2% and epinephrine 1/200000 and was injected in site of surgery before the start of operation .

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Gholamreza Khalili MD

Street address

Soffe Blvd

City

esfahan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoye Javanmard MD

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Grant name

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

Gholamreza khalili

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Esfahan University of Medical Sciences

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Person responsible for updating data

Contact

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Web page address

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

No more 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