Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 AND2,No history of seizure or psychologic problems or kidney disorders,No history of chronic using NSAID, opiod, 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

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Iran (Islamic Republic of)

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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
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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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Anesthesiology
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Person responsible for updating data

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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
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