Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Nov 2026

Comparative evaluation between two methods of induced hypotension including infusion of labetalol and lidocaine during tympanoplasty surgery

Protocol summary

Study aim
Comparative evaluation between two methods including induced hypotension with infusion of labetalol and lidocaine during tympanoplasty surgery

Design
Interventional study, double blind, with parallel group design. The sample size will be 64. Randomization will be done based on the table extracted from www.randomization.com site and using blocks of size 4.

Settings and conduct
Sixty four (64) patients candidate for Tympanoplasty will be recruited from Dastghaib and Khalili hospitals in Shiraz and will be divided into two groups of 32. In one group lidocaine and in the other group labetalol will be infused immediately after intubation until end of surgery. Patients are coded by the researcher based on the randomized list. Then the drug is prepared based on the list and will be provided to the anesthesia expert to give to each patient. In this way, the researcher, the patient and anesthesia expert and evaluators will be kept blind.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients undergoing tympanoplasty; being at the age range of 18-60 years old and class I,II ASA. Non Inclusion criteria: Drug sensitivity to Labetalol and Lidocain; history of hypertension and heart disorders; liver disorder; renal disorder; hormonal disorder; having chronic pain

Intervention groups
After induction & intubation, before injection of local anesthesia agent and surgical incision, In the first group, labetalol 0.5 % (Exir Co.), 20mg bolus will be injected during 2 minutes in supine position, then 0.5-2mg/min by syringe pump to max 300mg is infused. In the second group, a bolus dose of 1.5mg/kg lidocaine 1% (Exir Co.) will be injected in supine position during 2 minutes, then, 1.5mg/kg/h will be infused by syringe pump. It will be continued until reaching the proper pressure and until the end of the surgery in both groups.

Main outcome variables
Blood pressure level

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180922041084N3**
Registration date: **2019-03-01, 1397/12/10**
Registration timing: **prospective**

Last update: **2019-03-01, 1397/12/10**
Update count: **0**

Registration date
2019-03-01, 1397/12/10

Registrant information

Name
Maryam Tabibzadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-04-09, 1398/01/20

Expected recruitment end date
2019-07-11, 1398/04/20

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative evaluation between two methods of induced hypotension including infusion of labetalol and lidocaine during tympanoplasty surgery

Public title
Comparison of infusion of labetalol and lidocaine during tympanoplasty surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients undergoing tympanoplasty Being at the age range of 18-60 years old Being at class I and II ASA
Exclusion criteria:
Drug sensitivity to Labetalol and Lidocain History of hypertension and heart disorders Liver disorder Renal disorder Hormonal disorder Having chronic pain
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **64**
Randomization (investigator's opinion)
Randomized
Randomization description
Patient randomization will be done based on the table extracted from www.randomization.com site in the form of blocks of size 4.
Blinding (investigator's opinion)
Triple blinded
Blinding description
Patients are coded by the researcher based on the randomized list. Then the drug is prepared based on the list and will be provided to the anesthesia expert to assign to each patient. In this way, the researcher, the patient and anesthesia expert and evaluators will be kept blind.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shiraz University of Medical Sciences
Street address
Vice Chancellor of research, Shiraz University of Medical Sciences, 7th floor, central building of Shiraz University of Medical Sciences, Zand street
City
Shiraz
Province
Fars
Postal code
7134844119
Approval date
2018-12-24, 1397/10/03
Ethics committee reference number
IR.SUMS.MED.REC.1397.391

Health conditions studied

1

Description of health condition studied
Induced Hypotension
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Blood pressure level
Timepoint
Before and after induction of anesthesia,during operation and after operation
Method of measurement
By automatic blood pressure monitoring

Secondary outcomes

1

Description
Heart rate
Timepoint
Before and after induction and intraoperation and postoperation
Method of measurement
By pulse oximetry

2

Description
Arterial oxygen saturation
Timepoint

Before and after induction and intraoperation and postoperation

Method of measurement

By pulse oximetry

3

Description

End tidal co2

Timepoint

intraoperation

Method of measurement

By capnography

4

Description

Pain level

Timepoint

postoperation

Method of measurement

By visual analogue scale

5

Description

Surgen satisfaction level

Timepoint

Intraoperation

Method of measurement

By likert scale

6

Description

Dose of received fentanyl

Timepoint

intraoperation

Method of measurement

patient's document

Intervention groups

1

Description

Intervention group 1: in first group immediately after induction and intubation and before injection and surgical incision, labetalol 0.5 % (manufactured by Exire company) 20mg bolous during 2 minutes in supine position will be injected. Then infusion will be continued at the dose of 0.5_2mg/min to max 300mg or reaching the proper pressure by syringe pump until the end of surgery.

Category

Treatment - Drugs

2

Description

Intervention group 2: In the second group, immediately after the induction and intubation and before the injection of anesthesia and incision by the surgeon, a bolous dose of lidocaine 1% (manufacture by Exire company) will be injected bolously at the dose of 1_2 mg/kg body weight during 2 minutes in supine position and after that it will be continued at the dose of 1.5mg/kg body weight until the end of the operation.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Khalil Hospital

Full name of responsible person

Mehdi Rahmati

Street address

Khalili Street

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2

Recruitment center

Name of recruitment center

Dastghaib hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr.Younes Ghasemi

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Vice Chancellor of research, Shiraz University of Medical Sciences, 7th floor, central building of Shiraz

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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
Shiraz 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
Shiraz University of Medical Sciences

Full name of responsible person
Dr.Mehdi Haidari

Position
Anesthesiology resident/physician

Latest degree
Medical doctor

Other areas of specialty/work
Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
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Anesthesiologist

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Specialist

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Person responsible for updating data

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Full name of responsible person
Maryam Tabibzadeh

Position
Medical Doctor

Latest degree
Medical doctor

Other areas of specialty/work
Others

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available