

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 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 Lidocaine 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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7193635899

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2

Recruitment center

Name of recruitment center

Dastghaib hospital

Full name of responsible person

Mehdi Rahmati

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Eighth Avenue, Hafez Street

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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

Zinabosadat Fatahi saravi

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Anesthesiologist

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Specialist

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Person responsible for updating data

Contact

Name of organization / entity

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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