

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Comparative Study of the Effectiveness of Two Different Doses of Intravenous Labetalol on Cardiovascular Response to Tracheal Extubation

Protocol summary

Study aim

Determining and comparing the effect of 0.1 and 0.2 mg/kg of intravenous labetalol on the cardiovascular response to tracheal extubation

Design

This study is a randomized double blinded clinical trial with control group Which is performed on 72 patients who are candidates for elective surgery. The permutation block method is used for randomization.

Settings and conduct

Study place: Al-Zahra Hospital in Isfahan! Type of blindness: double blinded! method of blindness: The patient and the observer who collects the information will be unaware of the drug grouping! method: On about 72 patients (24 in each group) who are candidates for elective surgery in Al-Zahra Hospital 0.1, 0.2 mg/kg doses of intravenous labetalol and normal saline will be used.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Normotensive patients who are candidates for elective surgery less than two hours under general anesthesia requiring endotracheal intubation! age between 20 to 60 years! ASA one and two! informed consent to participate in the study! weight 55 to 45 kilogram. Exclusion criteria: pregnant women! diabetic patients! Patients with uncontrolled underlying cardiovascular disease! Baseline heart rate less than 60 beats per minute and systolic blood pressure less than 90 mm Hg! Patients with cerebrovascular diseases! contraindication of the use of study drugs! known allergy to anesthesia drugs of the study! opioid abuse! Taking drugs with cardiovascular effects

Intervention groups

Intervention group 1: Labetalol (0.1 mg/kg diluted with 0.9% saline to 5 ml) Intervention group 2: Labetalol (0.2mg/kg diluted with 0.9% saline to 5 ml) Control group: 5ml saline 0.9%

Main outcome variables

Systolic blood pressure! Diastolic blood pressure! Median

arterial blood pressure! Heart rate! O2 saturation

General information

Reason for update

Evaluation of the effect of lower doses of labetalol on hemodynamic response to endotracheal tube extubation

Acronym

IRCT registration information

IRCT registration number: **IRCT20180416039326N16**
Registration date: **2020-11-30, 1399/09/10**
Registration timing: **prospective**

Last update: **2022-01-02, 1400/10/12**

Update count: **1**

Registration date

2020-11-30, 1399/09/10

Registrant information

Name

Hamidreza Shetabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-19, 1399/10/30

Expected recruitment end date

2021-05-21, 1400/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative Study of the Effectiveness of Two Different Doses of Intravenous Labetalol on Cardiovascular Response to Tracheal Extubation

Public title

Comparative Study of the Effectiveness of Two Different Doses of Intravenous Labetalol on Cardiovascular Response to Tracheal Extubation

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Normotensive patients who are candidates for elective surgery less than two hours under general anesthesia requiring endotracheal intubation Age between 20 to 60 years ASA one and two Informed consent to participate in the study Weight 55 to 85 kilogram

Exclusion criteria:

Pregnant women Diabetic patients Patients with uncontrolled underlying cardiovascular disease Baseline heart rate less than 60 beats per minute and systolic blood pressure less than 90 mmHg Patients with cerebrovascular diseases Contraindication of the use of study medicines Known allergy to anesthetics in the study Opioid abuse Taking medicines with cardiovascular effects

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

By using a list of random numbers generated by computer, patients are assigned to each three groups based on the permutation blocks method with blocks with a volume of 6.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient and the observer who collects the information will be unaware of the drug grouping.

Placebo

Not 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

Hezarjarib Blvd, Isfahan University of Medical Sciences

City

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Postal code

8174673461

Approval date

2020-10-17, 1399/07/26

Ethics committee reference number

IR.MUI.MED.REC.1399.633

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

Tracheal Extubation

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Systolic blood pressure

Timepoint

Before extubation and 1, 3, 5 and 10 minutes after extubation

Method of measurement

Barometer

2**Description**

Diastolic blood pressure

Timepoint

Before extubation and 1, 3, 5 and 10 minutes after extubation

Method of measurement

Barometer

3**Description**

Pulse rate

Timepoint

Before extubation and 1, 3, 5 and 10 minutes after extubation

Method of measurement

Pulse oximetry

4

Description

Oxygen saturation percentage

Timepoint

Before extubation and 1, 3, 5 and 10 minutes after extubation

Method of measurement

Pulse oximetry

5

Description

Mean arterial pressure

Timepoint

Before extubation and 1, 3, 5 and 10 minutes after extubation

Method of measurement

Barometer

Secondary outcomes

1

Description

Duration of staying in recovery

Timepoint

Based on minutes from arrival to reaching the modified aldrete score of 9

Method of measurement

Information collection form

2

Description

Adverse airway response

Timepoint

During the time of staying in recovery

Method of measurement

Information collection form

3

Description

Hemodynamic complications

Timepoint

During the time of staying in recovery

Method of measurement

Information collection form

4

Description

Duration of extubation

Timepoint

Based on minutes from the time of discontinuing anesthetics to the time of extubation

Method of measurement

Information collection form

Intervention groups

1

Description

Intervention group 1: In this group, a syringe containing labetalol (0.1 mg / kg diluted with 0.9% saline to a volume of 5 ml) will be injected.

Category

Treatment - Drugs

2

Description

Intervention group 2: In this group, a syringe containing labetalol (0.2 mg / kg, diluted with 0.9% saline to a volume of 5 ml) will be injected.

Category

Treatment - Drugs

3

Description

Control group: In this group Syringe containing 5 ml of 0.9% saline will be injected.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-zahra hospital

Full name of responsible person

Hamidreza Shetabi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghju javanmard

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Vice chancellor of research and technology of
university.Isfahan University of Medical Sciences.
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Grant name**Grant code / Reference number****Is the source of funding the same sponsor
organization/entity?**

No

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

Hamidreza Shetabi

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Latest degree

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Other areas of specialty/work

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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

Yes - There is 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

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

Title and more details about the data/document

Unidentifiable individual data including hemodynamic indices and complications in all three groups can be shared.

When the data will become available and for how long

6 months after publication of paper

To whom data/document is available

Academic and medical researchers

Under which criteria data/document could be used

Use for research and treatment purposes

From where data/document is obtainable

Email of the person in charge of public accountability:
Hamidshetabi@med.mui.ac.ir Dr Hamidreza Shetabi

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

If possible, it will be sent via email up to a maximum of 1 month after applying.

Comments