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 hematodynamic 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

+98 31 3620 2020

Email address

hamidshetabi@med.mui.ac.ir

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
Isfahan
Province
Isfehan
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

Street address

Al-Zahra Hospital; Sofe bolevard

City

Isfahan

Province

Isfehan

Postal code

8174675731

Phone

+98 31 3620 1818

Email

hamidshetabi@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghju javanmard

Street address

Vice chancellor of research and technology of university.Isfahan University of Medical Sciences. Hezarjarib St

City
Isfahan

Province
Isfehan

Postal code
۷۳۴۶۱-۸۱۷۴۶

Phone
+98 31 3668 8138

Email
research@mui.ac.ir

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

Street address
Al-Zahra Hospital; Sofe bolevard

City
Isfahan

Province
Isfehan

Postal code
8174675731

Phone
+98 31 3620 2020

Email
hamidshetabi@med.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Hamidraza Shetabi

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

Street address
Al-Zahra Hospital; Sofe bolevard

City
Isfahan

Province
Isfehan

Postal code
8174675731

Phone
+98 31 3620 2020

Email
hamidshetabi@med.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Hamidreza Shetabi

Position
Associate proffesor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

Street address
Al-Zahra Hospital; Sofe bolevard

City
Isfahan

Province
Isfehan

Postal code
8174675731

Phone
+98 31 3620 2020

Email
hamidshetabi@med.mui.ac.ir

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