Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of the effect of intravenous labetalol administration with intravenous lidocaine on hemodynamic variables during laryngoscopy and endotracheal intubation and postoperative nausea and vomiting in female patients undergoing abdominal surgery

Protocol summary

Study aim
Comparison of the effect of intravenous labetalol administration with intravenous lidocaine on hemodynamic variables during laryngoscopy and endotracheal intubation and postoperative nausea and vomiting in female patients undergoing abdominal surgery

Design
This study is a one-blind randomized clinical trial, without control group, with parallel group and phase 2-3, in which 64 patients are randomly divided into 2 groups of 32 using a random number table.

Settings and conduct
This trial is performed by a researcher in the Kowsar operating room of Shahid Sadoughi Hospital in Yazd, in 2 groups of 32 people. Patients do not know the type of drug, In the first group, Labetalol and the second group, lidocaine is injected intravenously. The mentioned hemodynamic variables are measured in the times; immediately before the injection of drug and laryngoscopy, immediately after endotracheal intubation, immediately after skin incision and the result is recorded in the questionnaire. side effects; Bradycardia, hypotension, nausea and vomiting are evaluated and recorded in a questionnaire. Finally, the results are analyzed by SPSS software and relevant statistical tests

Participants/Inclusion and exclusion criteria
Inclusion: All women Who candidate for abdominal surgery, American Society of Anesthesiologists(ASA class1&2) Exclusion: patients with arterial hypertension، ischemic heart disease، sever heart disease pulmonary، liver and renal disease and addiction

Intervention groups
Intervention group1: Intravenous infusion labetalol 10mg immediately before general anesthesia Intervention group2: Intravenous infusion lidocaine at a dose of 1.5mg/kg immediately before general anesthesia

Main outcome variables
Changes in mean arterial, diastolic, systolic blood pressure and heart rate; Determining and comparing the incidence of side effects: bradycardia and hypotension;And incidence of vomiting and nausea

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20100102002963N30**
Registration date: **2021-04-24, 1400/02/04**
Registration timing: **prospective**

Last update: **2021-04-24, 1400/02/04**
Update count: **0**

Registration date
2021-04-24, 1400/02/04

Registrant information

Name
Shekoufeh Behdad

Name of organization / entity
Shahid Sadoughi University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 35 1822 1386

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-05-10, 1400/02/20
Expected recruitment end date
2021-07-11, 1400/04/20
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of intravenous labetalol administration with intravenous lidocaine on hemodynamic variables during laryngoscopy and endotracheal intubation and postoperative nausea and vomiting in female patients undergoing abdominal surgery

Public title
Comparison of the effect of intravenous labetalol administration with intravenous lidocaine on hemodynamic variables and postoperative nausea and vomiting
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All women candidates for abdominal surgery All women between the ages of 25 and 65 years All women with systolic blood pressure between 90 mm hg and 160 mm Hg All women with normal body mass index All women with diastolic blood pressure between 70 and 100 mm Hg American Society of Anesthesiologists (ASA) class 1 :a normal healthy patient ,for Example: Fit, nonobese (BMI under 30), a nonsmoking patient with good exercise tolerance. American Society of Anesthesiologists (ASA) class 2 : a patient with a mild systemic disease ,for Example: Patients with no functional limitations and a well-controlled disease (for example treated hypertension, obesity with BMI under 35, frequent social drinker or a cigarette smoker)
Exclusion criteria:
Arterial hypertension Ischemic heart disease Heart failure Pulmonary disease Addiction Renal disease Liver disease
Age
From **25 years** old to **65 years** old
Gender
Female

Phase
2-3
Groups that have been masked

- Participant

Sample size
Target sample size: **64**
Randomization (investigator's opinion)
Randomized
Randomization description
In order to randomly allocate 64 eligible applicants, we randomly divide them into two groups of 32 people. For this purpose, we use Random allocation software version 1.0 under Windows to create a sequence, and by using this software we make A list which is specified from 1 to 64 with group A or B treatment By Using this list, we give the first person who is eligible to enter the study, number one and the last person the number 64, then based on the random allocation list and by the software, it is determined which group A or B each person is in.
Blinding (investigator's opinion)
Single blinded
Blinding description
This study is a single-blind randomized clinical trial in which patients are unaware of the type of drug being prescribed, so that the two drugs are prepared and coded in two identical syringes. And according to random numbers, the specified code is given to the patients
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Ali Ibn Abi Talib Medical School (AS), Islamic Azad University, Yazd Branch
Street address
Safaieh, Boulevard of the Shohadaie Gomnam
City
Yazd
Province
Yazd
Postal code
8915813135
Approval date
2020-06-29, 1399/04/09
Ethics committee reference number
IR.IAU.YAZD.REC.1399.028

Health conditions studied

1

Description of health condition studied
Comparison of the effect of intravenous labetalol with intravenous lidocaine on hemodynamic variables during laryngoscopy and endotracheal intubation and postoperative nausea and vomiting in patients undergoing abdominal surgery
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Changes in systolic blood pressure
Timepoint
Immediately before drug injection Immediately before laryngoscopy Immediately after intubation Immediately after skin incision
Method of measurement
Operating room monitoring with Blood pressure cuf connected to the monitor and recording information in a questionnaire

2

Description
Determining and comparing the incidence of bradycardia (heart rate <50)
Timepoint
Immediately after the operation in recovery room
Method of measurement
Monitoring in the recovery room with a blood pressure monitor connected to the monitor and recording information in a questionnaire

3

Description
Determining and comparing the incidence of vomiting and nausea
Timepoint
Immediately after the operation in recovery room
Method of measurement
Question from the patient and registration in the questionnaire

4

Description
Changes in diastolic blood pressure
Timepoint
Immediately before drug injection Immediately before laryngoscopy Immediately after intubation Immediately after skin incision
Method of measurement
Operating room monitoring with Blood pressure cuff connected to the monitor and recording information in a questionnaire

5

Description
Changes in mean arterial blood pressure
Timepoint
Immediately before drug injection Immediately before laryngoscopy Immediately after intubation Immediately after skin incision
Method of measurement
Operating room monitoring with Blood pressure cuff connected to the monitor and recording information in a questionnaire

6

Description
changes in heart rates
Timepoint
Immediately before drug injection Immediately before laryngoscopy Immediately after intubation Immediately after skin incision
Method of measurement
Operating room monitoring with Blood pressure cuff connected to the monitor and recording information in a questionnaire

7

Description
Determining and comparing the incidence of hypotension side effects (systolic blood pressure < 9) or a drop of more than 20% of the base rate
Timepoint
Immediately after the operation in recovery room
Method of measurement
Monitoring in the recovery room with a blood pressure monitor connected to the monitor and recording information in a questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group1: In this group, 10 mg of labetalol, from Kern pharma company is injected intravenously and once immediately before induction of general anesthesia to eligible patients.
Category
Treatment - Drugs

2

Description
Intervention group2: In this group, lidocaine 1.5 mg per kg body weight of the patient, from Caspian tamin company is injected intravenously and once immediately before induction of general anesthesia to eligible patients.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Sadoughi Hospital
Full name of responsible person
Dr Shekoufeh Behdad
Street address

Shahid Sadoughi Hospital, Ebnesina Blv, Safayieh, Yazd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Azad Islamic University Of Yazd

Full name of responsible person
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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
Azad Islamic University Of Yazd

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
Yazd University of Medical Sciences

Full name of responsible person
Dr. Shekoufeh Behdad

Position
Professor, Depatment of anestesiology

Latest degree
Specialist

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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Position
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Person responsible for updating data

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Position
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Anesthesiology

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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