Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jul 2026

Comparison of the effect of intravenous Esmolol and intravenous Lidocaine on hemodynamic variables during laryngoscopy and tracheal intubation and postoperative nausea and vomiting in patients undergoing abdominal surgery

Protocol summary

Study aim

Comparison of the effect of intravenous Esmolol 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 2 intervention parallel groups 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 criteria: All female patients who are candidates for gynecological abdominal surgery Exclusion criteria: arterial hypertension, ischemic heart disease, severe heart disease, ASA Class I, II, pulmonary, renal, hepatic, addiction.

Intervention groups

A total of 64 patients are randomly divided into two groups of 32 using a random number table. In the first group, intravenous osmolol (0.5 mg / kg) is injected immediately before induction of general anesthesia and in the second group, intravenous lidocaine (1.5 mg / kg) is injected.

Main outcome variables

Hemodynamic variables including systolic, diastolic, mean arterial blood pressure and heart rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100102002963N32**
Registration date: **2021-06-12, 1400/03/22**
Registration timing: **registered_while_recruiting**

Last update: **2021-06-12, 1400/03/22**
Update count: **0**

Registration date

2021-06-12, 1400/03/22

Registrant information

Name

Shekoufeh Behdad

Name of organization / entity

Shahid Sadoughi University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 35 1822 1386

Email address

drbehdad@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2021-06-06, 1400/03/16
Expected recruitment end date
2021-07-07, 1400/04/16
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of intravenous Esmolol and intravenous Lidocaine on hemodynamic variables during laryngoscopy and tracheal intubation and postoperative nausea and vomiting in patients undergoing abdominal surgery

Public title
Effect of intravenous Esmolol and intravenous Lidocaine on hemodynamic variables during laryngoscopy and tracheal intubation and postoperative nausea and vomiting
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All female patients are candidates for gynecological abdominal surgery
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 creat 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 oerson who is eligible to enter the study, number 1 and the last person the number 64, then based on the random allocation list and by the software, it is determinded which group A or B each person is in.
Blinding (investigator's opinion)
Single blinded
Blinding description
Only patients are unaware of how to group and the amount and type of medication used It is necessary to mention in this research the drugs used and Their levels in both experimental groups are completely routine and tested The only side effects of the drug from the time of injection of the drug until the end of its effect and Nausea and vomiting are assessed in two groups and recorded if they occur.
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
2020-08-09, 1399/05/19
Ethics committee reference number
IR.IAU.YAZD.REC.1399.029

Health conditions studied

1

Description of health condition studied
Comparison of the effect of intravenous osmolol and intravenous lidocaine on hemodynamic variables during laryngoscopy and tracheal 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 endotracheal 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

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 endothracheal 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 infirmation in a questionnaire

6

Description
Changes in heart rates
Timepoint
Immediately before drug injection Immediately before laryngoscoy Immediately after endothracheal 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 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 group 1: In this group, 0.5 mg/kg of Esmolol, from Myungmoon pharmaceutical Co., Ltd is injected intravenously and once immediately before induction of general anesthesia to eligible patients.
Category
Treatment - Drugs

2

Description
Intervention group 2: 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, Yazd
Full name of responsible person
Dr. Shokoofeh Behdad
Street address
Ibn Sina Street, Shahid Ghandi Boulevard, Safaieh
City
YAZD
Province
Yazd
Postal code
8915887857
Phone
+98 35 3822 4000
Fax

+98 35 3822 4100

Email
sadoghi-hospital@ssu.ac.ir

Web page address
https://web.ssu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Azad Islamic University Of Yazd

Full name of responsible person
Dr Seyed Mohammadreza Mortazavi Zade

Street address
Boulevard of the Shohadaie Gomnam, Safaieh

City
Yazd

Province
Yazd

Postal code
8915813135

Phone
+98 35 3187 2200

Fax
+98 35 3821 5034

Email
info@iauyazd.ac.ir

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
Private

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 of Anesthesiology

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

Street address
Shahid Sadoughi Hospital, Ebnesina Blv, Safayieh, Yazd

City
YAZD

Province
Yazd

Postal code
8915887857

Phone
+98 35 3822 4101

Email
behdad90@gmail.com

Web page address
https://web.ssu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Yazd University of Medical Sciences

Full name of responsible person
Dr Shekofeh Behdad

Position
Professor of Anesthesiology

Latest degree
Specialist

Other areas of specialty/work
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Street address
Shahid Sadoughi Hospital, Ebnesina Blv, Safayieh, Yazd

City
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Province
Yazd

Postal code
8915887857

Phone
+98 35 3822 4101

Email
behdad90@gmail.com

Web page address
https://web.ssu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Yazd University of Medical Sciences

Full name of responsible person
Dr Shekofeh Behdad

Position
Professor of Anesthesiology

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Street address
Shahid Sadoughi Hospital, Ebnesina Blv, Safayieh, Yazd

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Postal code

8915887857

Phone

+98 35 3822 4101

Email

behdad90@gmail.com

Web page address

https://web.ssu.ac.ir

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