Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of push dose Epinephrine on mortality rate following intubation in hypotensive patients

Protocol summary

Study aim
Effect of push dose Epinephrine on mortality rate following intubation in hypotensive patients

Design
Clinical trial with a historical control group, without blinding and randomization, on 60 patients

Settings and conduct
For 30 intubated patients referred to the emergency department of Yazd Shahid Sadoughi Hospital who have inclusion criteria, Epinephrine is injected through a peripheral vein, until SBP raise to 90 mm of mercury or MAP raise to 65 mm of mercury. If side effects occur, Epinephrine will be discontinued.

Participants/Inclusion and exclusion criteria
Inclusion criteria is age more than 14 and less than 65; systolic blood pressure (SBP) less than 90 mm of mercury or mean arterial pressure (MAP) less than 65 mm of mercury. Exclusion criteria is pregnancy and heart rate more than 180 beat per minute.

Intervention groups
We will choose 30 patient for case group from intubated patients referred to the emergency department of Yazd Shahid Sadoughi Hospital. For these patients Epinephrine will be injected every two minutes until SBP raise to 90 mm of mercury or MAP raise to 65 mm of mercury, 30 patients in control group will be selected from patients who had inclusion and exclusion criteria, and were intubated 1 years ago in the emergency department of Yazd Shahid Sadoughi or Shahid Rahnemoun Hospital.

Main outcome variables
Systolic and diastolic blood pressure; heart rate; receiving vasoactive drug in the first 24 hours (Epinephrine or other drugs); side effects of Epinephrine injection; mortality rate in the first 24 hours

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200809048341N2**
Registration date: **2020-12-10, 1399/09/20**
Registration timing: **prospective**

Last update: **2020-12-10, 1399/09/20**
Update count: **0**

Registration date
2020-12-10, 1399/09/20

Registrant information

Name
Soheila Azimi Aabarghouei

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 35 3828 2682

Email address
s.azimi@ssu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-12-21, 1399/10/01

Expected recruitment end date
2021-03-21, 1400/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of push dose Epinephrine on mortality rate following intubation in hypotensive patients

Public title

Effect of Epinephrine in treatment of hypotension of intubation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

systolic blood pressure lesser than 90 mmHg or mean arterial pressure lesser than 65 mmHg

Exclusion criteria:

pregnancy heart rate more than 180 beat per minute

Age

From **14 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research ethics committee of school of medicine _ shahid sadoughi university of medical sciences

Street address

Central building of Shahid Sadoughi university of medical sciences, Bahonar square, Yazd

City

Yazd

Province

Yazd

Postal code

89416978477

Approval date

2019-08-27, 1398/06/05

Ethics committee reference number

IR.SSU.MEDICINE.REC.1399.022

Health conditions studied

1

Description of health condition studied

mortality following intubation in hypotensive patients

ICD-10 code

T88.4XXA

ICD-10 code description

Failed or difficult intubation, initial encounter

Primary outcomes

1

Description

Percentage of people whose systolic blood pressure reaches above 90 mm of mercury or mean arterial pressure reaches above 65 mm of mercury after epinephrine administration.

Timepoint

30 minutes before until 1 hour after intubation when the patient has a systolic blood pressure less than 90 mm of mercury or a mean arterial pressure less than 65 mm of mercury.

Method of measurement

Mercury sphygmomanometer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For 30 patients who have SBP less than 90 mm of mercury or MAP less than 65 mm of mercury in 30 minutes before to 1 hour after intubation, a push dose of Epinephrine at a concentration of 1/100000 at 1cc every 2 minutes will be injected to the peripheral vessel until SBP become above 90 or MAP become above 65 mm of mercury. In addition, patients' blood pressure will be checked manually with a Mercury sphygmomanometer. Vital signs are measured and recorded 30 minutes before intubation and then every 15 minutes to 1 hour after intubation and at the end of 24 hours. If the side effects of Epinephrine happened, the administration will be discontinued.

Category

Treatment - Drugs

2

Description

Control group: The control group will be selected from 30 patients who underwent intubation in the emergency department of Yazd Shahid Sadoughi or Shahid Rahnemoun Hospital one year before the start of the study and met the inclusion and exclusion criteria. If these patients have a defective record, they will be removed from the study.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Sadoughi Hospital
Full name of responsible person
Soheila Azimi Abarghouei
Street address
Emergency Department, Ebne Sina Blvd, Yazd
City
Yazd
Province
Yazd
Postal code
8913893111
Phone
+98 35 3828 2682
Email
S.azimi@ssu.ac.ir

2

Recruitment center

Name of recruitment center
Shahid Rahnemoon Hospital
Full name of responsible person
Soheila Azimi Abarghouei
Street address
Farrokhi St, Yazd
City
Yazd
Province
Yazd
Postal code
8913893111
Phone
+98 35 3828 2682
Email
S.azimi@ssu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Dr.Masoud Mirzaei
Street address
Central building of Shahid Sadoughi University of Medical Sciences, Bahonar Square, Yazd
City
Yazd
Province
Yazd
Postal code
۸۹۱۶۹۷۸۴۷۷
Phone
+98 35 3724 0171
Email
Info@ssu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Yazd 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
Yazd University of Medical Sciences
Full name of responsible person
Fatemeh Sadat Mohammadi Hanzaie
Position
Medical student
Latest degree
A Level or less
Other areas of specialty/work
General Practitioner
Street address
Dead End 22, Naeem Abad St., Kashani St.
City
Yazd
Province
Yazd
Postal code
8916768759
Phone
+98 35 3824 9596
Email
frozenfsm@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Soheila Azimi Aabarghouei
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Emergency Medicine
Street address

Emergency ward, Shahid Sadoughi Hospital, Ebne sina Blvd.

City
Yazd

Province
Yazd

Postal code
8913893111

Phone
+98 35 3828 2682

Email
S.azimi@ssu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Yazd University of Medical Sciences

Full name of responsible person
Fatemeh Sadat Mohammadi Hanzaie

Position
Medical Student

Latest degree
A Level or less

Other areas of specialty/work
General Practitioner

Street address
Dead End 22, Naeem Abad St., Kashani St.

City
Yazd

Province
Yazd

Postal code
8916768759

Phone
+98 35 3824 9596

Email
frozenfsm@gmail.com

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