

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of pneumatic pumps on hypotension due to Midazolam and Fentanyl in patients admitted to the ICU

Protocol summary

Study aim

Variations of hypotension

Design

In this clinical study, 56 patients will be selected randomly and they will be divided into treatment and control groups using permuted block technique (4 patients in each block)

Settings and conduct

This research will be done on the patients hospitalized in ICU of "Bohloul" hospital that divided into control and treatment groups using one sided blind method

Participants/Inclusion and exclusion criteria

Inclusion criteria Hospitalized in ICU under mechanical ventilation; Having order to receive 0.01-0.05 mg/kg of "Midazolam" and 5 µg/kg of "Fentanyl" Exclusion criteria Making an unstable status while doing treatments

Intervention groups

Pneumatic pump's cuff will be applied on treatment group in 3 phases, each phase 1 minute (45 seconds under pressure and 15 seconds of discharge) and there will be no treatment in control group by the researcher

Main outcome variables

Variations of hypotension

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190225042836N1**

Registration date: **2019-04-16, 1398/01/27**

Registration timing: **registered_while_recruiting**

Last update: **2019-04-16, 1398/01/27**

Update count: **0**

Registration date

2019-04-16, 1398/01/27

Registrant information

Name

Amir Bagherzadeh bahabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 5722 4058

Email address

bagherzadeh.a.stu@gm.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-06, 1397/12/15

Expected recruitment end date

2019-07-22, 1398/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of pneumatic pumps on hypotension due to Midazolam and Fentanyl in patients admitted to the ICU

Public title

The Effect of using Pneumatic Pump on the Hypotension due to sedation in Patients Admitted to the ICU

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Hospitalized in ICU under mechanical ventilation Written consent form from patient's relatives (first degree relative) Having order to receive 0.01-0.05 mg/kg "Midazolam" and 5 µg/kg "Fentanyl" 20 percent decrease in non-invasive blood pressure (MAP-SBP) to the initial

non-invasive blood pressure No ulcers, skin or vascular effects or fractures in the legs Stable hemodynamics according to the ICU specialists No Cardiovascular failure according to the patients medical history Patients should be 20-80 years old

Exclusion criteria:

Making an unstable status while doing treatment
Contraindications for "Midazolam" or "Fentanyl" or both of them

Age

From **20 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Investigator

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

From the research community who has the inclusion criteria, participants will be selected randomly and they will be divided into treatment and control groups using permuted block technique (4 patients in each block)

Blinding (investigator's opinion)

Single blinded

Blinding description

Non-invasive blood pressure will be measured by someone except the researcher

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Gonabad University of Medical Sciences

Street address

Gonabad University of Medical Sciences, Mahdizadeh Blvd.

City

Gonabad

Province

Razavi Khorasan

Postal code

969117433

Approval date

2019-02-20, 1397/12/01

Ethics committee reference number

IR.GMU.REC.1397.119

Health conditions studied

1

Description of health condition studied

Unspecified disorders of the circulatory system

ICD-10 code

I95.2

ICD-10 code description

Hypotension due to drugs

Primary outcomes

1

Description

Non-invasive blood pressure variations

Timepoint

Measuring non-invasive blood pressure before, instantly, 3 and 5 minutes after treatments

Method of measurement

Monitoring device

Secondary outcomes

1

Description

heart beat variation

Timepoint

Measuring heart beat before, instantly, 3 and 5 minutes after treatments

Method of measurement

Monitoring device

Intervention groups

1

Description

Intervention group: In supine mode, on patients that are hospitalized in ICU and receive "Midazolam" and "Fentanyl" according to the specialist's order, Pneumatic pump will be applied in 3 phases and under 35-45 mmHg pressure, each phase 1 minute (45 seconds under pressure and 15 seconds of discharge)

Category

Treatment - Other

2

Description

Control group: There will be no treatment in this group by the researcher

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Bohloul hospital

Full name of responsible person

Amir Bagherzadeh bahabadi

Street address

'Bohloul" hospital, Vahdat blvd.

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Fax

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Email

bohloulhospital@gmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Dr. Shahla Khosravan

Street address

Vice chancellor for research, Gonabad University of
Medical Sciences, Gonabad

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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

Gonabad 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

Gonabad University of Medical Sciences

Full name of responsible person

Amir Bagherzadeh Bahabadi

Position

Critical Care Nursing Graduate Student

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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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

Yes - There is a plan to make this available

Title and more details about the data/document

A part of data

When the data will become available and for how long

6 months after publishing results

To whom data/document is available

Academic and Scientific researchers

Under which criteria data/document could be used

Observation of ethical principles from documentations

From where data/document is obtainable

bagherzadeh.a.stu@gmu.ac.ir - 00989159361026 -
00985157221488

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

Phone call 0098 915 9361026

Comments