Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of plus pressuer variation and plus oximetry oscillation in the prediction of the response of fluid therapy in traumatic patients connectedto ventilators admitted in intensive care uint

Protocol summary

Study aim

Comparison of pulse pressure and oximeter pulse fluctuations in predicting fluid therapy response in ventilator-connected patients admitted to the intensive care unit

Design

The sample size for the study is to examine the area under the ROC curve: Using Medcalc software and considering the area under the curve 0.80 as the optimal area under the curve, the type I error was 0.05 and the power of 90% (type II error 0.10) of the sample size in each Responder and Non responder group was 17. Finally, in order to increase the power to 95% of the sample size, each group was considered 20 people and 40 people in total.Sampling will be done through available sampling and 40 patients will be enrolled according to inclusion criteria.

Settings and conduct

This is a clinical trial study of diagnostic methods. The study population will be trauma patients undergoing mechanical ventilation admitted to the intensive care unit of Bahonar Hospital.

Participants/Inclusion and exclusion criteria

Ventilator Connected Patients With control Breathing Admitted to intensive Care Ages 18 to 80 years old. And they have no heart problems. And they are not pregnant.

Intervention groups

The number of people included in this study is 40 people. After selecting and adjusting the ventilator for the patient, treatment with 250 cc ringer begins. Due to the increase in MAP, it is divided into two groups: responders and non-responders to fluid therapy. Then PPV changes in pulse oximetry and arterline waves are investigated.

Main outcome variables

1-Pulse pressure and oximeter pulse fluctuations vary with age. 2. Pulse pressure and oximeter pulse oscillations vary by sex. 3. Pulse pressure and oximeter pulse oscillations vary by weight. 4. Pulse pressure and oximeter pulse fluctuations vary in height

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190720044284N1**
Registration date: **2021-01-12, 1399/10/23**
Registration timing: **prospective**

Last update: **2021-01-12, 1399/10/23**
Update count: **0**

Registration date

2021-01-12, 1399/10/23

Registrant information

Name

yousef Arefi Maskoni

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3226 5439

Email address

y.arefi@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-19, 1399/12/01

Expected recruitment end date

2021-04-21, 1400/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of plus pressuer variation and plus oximetry oscillation in the prediction of the response of fluid therapy in traumatic patients connectedto ventilators admitted in intensive care uint

Public title

comparison of plus pressuer variation and plus oximetry oscillation in the prediction of the response of fluid therapy in traumatic patients connectedto ventilators admitted in intensive care uint

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:

Patients hospitalized in intensive care units Ages 18 to 80 years Breathing control with a tidal volume of 8 to 10 cc / kg Lack of advanced heart and respiratory disease

Exclusion criteria:

Dissatisfaction with patient companions Spontaneous breathing Under 18 and over 80 years Being pregnant

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients or their patient's companions are not aware of other patients and interventions performed.

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committe of Kerman University of Medical Sciences

Street address

Kerman, Qarni St. - Shahid Bahonar Hospital

City

Kerman

Province

Kerman

Postal code

7613747181

Approval date

2020-11-23, 1399/09/03

Ethics committee reference number

IR.KMU.REC.1399.468

Health conditions studied

1

Description of health condition studied

comparison of plus pressuer variation and variation in the amplitud of the plus oximetry plethysmographic waveform(◇POP) in the prediction of the response of fluid therapy in traumatic patients connected to ventilators admitted in intensive care uint

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pulse pressure variation

Timepoint

At the beginning of the intervention and 45 minutes after the intervention

Method of measurement

The difference between the maximum pulse pressure and the minimum pulse pressure is divided by half the sum of the maximum pulse pressure and the minimum pulse pressure and the result will be multiplied by 100. (Pulse pressure is the difference between systolic and diastolic blood pressure from one heartbeat to the next. Pulse oximetry will be recorded on the arterial pressure monitoring chart.

Secondary outcomes

empty

Intervention groups

1

Description

Category

empty

2

Description

Intervention group: For all trauma patients admitted to the intensive care unit who are under mechanical

ventilation, before the start of fluid therapy (according to the protocol) pulse pressure fluctuations according to the above formula and pulse oximetry and arterial pressure of the patient MAP, SBP, PR, RR will be measured. Treatment is started for the patient (250 cc of crystalloid serum) then after 45 minutes the patient's pulse pressure and pulse oximetry fluctuations will be measured again and patients according to the response to fluid therapy into two groups Responder (increase in MAP more than 15% Non responder is divided and ppv changes are measured based on atraline waves and pulse oximetry. The patient's condition will also be recorded in response to fluid therapy.

Category
Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Bahonar Hospital, Qarni St. ,Kerman

Full name of responsible person
Mehdi Ahmadinejad

Street address
Shahid Bahonar Hospital, Qarni St. ,Kerman

City
Kerman

Province
Kerman

Postal code
7613747181

Phone
+98 34 3223 5011

Email
mahmadinejad @kmu.ac.ir

Web page address
http://bh.kmu.ac.ir/fa

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Mehdi Ahmadinjad

Street address
Kerman, Qarni St. - Shahid Bahonar Hospital

City
Kerman

Province
Kerman

Postal code
7613747181

Phone
+98 34 3223 5011

Email
Yosef.am@gmall.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Kerman 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
Kerman University of Medical Sciences

Full name of responsible person
Mehdi Ahmadinejad

Position
Associate Professor

Latest degree
Subspecialist

Other areas of specialty/work
Anesthesiology

Street address
Shahid Bahonar Hospital, Qarni St. ,Kerman

City
Kerman

Province
Kerman

Postal code
7613747181

Phone
+98 34 3223 5011

Email
mahmadinejad@kmu.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Yousef Arefi Maskoni

Position
resident

Latest degree
Medical doctor

Other areas of specialty/work
Anesthesiology

Street address
Shahid Bahonar Hospital, Qarni St. ,Kerman

City
Kerman

Province
Kerman
Postal code
7613747181
Phone
+98 34 3223 5011
Email
Yosef.am@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Yousef Arefi Maskoni
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
Street address
Shahid Bahonar Hospital,Qarni St. ,Kerman
City
Kerman
Province
Kerman
Postal code
7613747181
Phone
+98 34 3223 5011
Email
Yosef.am67@gmall.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no more information
Study Protocol
No - There is not 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
No - There is not 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
No - There is not a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available