# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 Jun 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)

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**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**
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## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**
Kerman University of Medical Sciences
**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?**
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
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## 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