Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Jun 2026

Comparison of two fluid therapy methods with and without Lasix in crash injuries with lung contusion referred to Kerman Bahonar Hospital in 2023

Protocol summary

Study aim

Determination of the effect of two fluid therapy methodes with and without Lasix in crash injuries with lung contusion referred to Kerman Shahid Bahonar Hospital

Design

Clinical trial with control and intervention parallel groups, double blinded, randomized and phase 2 on 26 patients

Settings and conduct

This clinical trial includes patients aged 18-60 with crash injuries referred to Kerman Bahonar Hospital. After checking the inclusion and exclusion criteria, people will be divided into two groups, receiving crystalloids (normal saline) and crystalloids accompanied with furosemide (Lasix). The study design is double blinded, and participants as well as researchers are not aware of the allocation of the groups. The checklist of relevant variables will be completed for each patient at the beginning of the study and every three hours after receiving treatment for 48 hours.

Participants/Inclusion and exclusion criteria

Inclusion criteria: adult patients (over 18 years old) with pulmonary contusion and Creatine Kinase values >5000 I/U due to multiple trauma present in the first six hours of trauma. Exclusion criteria: Myocardial contusion; organ failure; chronic pulmonary disease; pulmonary embolism; need for massive transfusion; complications of of blood transfusion; spinal cord injury; acute kidney injury; not willing to participate in the study; death within the first 48 hours.

Intervention groups

Control group: fluid therapy according to the defined protocol. Intervention group: fluid therapy according to the protocol with furosemide (2 mg/hour infusion) added after three hours of fluid initiation.

Main outcome variables

Systolic blood pressure; diastolic blood pressure; mean arterial pressure; pulse rate; respiratory rate; arterial PaO2; serum sodium; creatine kinase; serum creatinin; intra-abdominal pressure; need for intubation; PaO2/FiO2 ratio; Intake/Output.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20101220005426N14**
Registration date: **2023-03-24, 1402/01/04**
Registration timing: **registered_while_recruiting**

Last update: **2023-03-24, 1402/01/04**
Update count: **0**

Registration date

2023-03-24, 1402/01/04

Registrant information

Name

Mehdi Ahmadinejad

Name of organization / entity

Anesthesiology department, Kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-20, 1401/12/01

Expected recruitment end date

2024-02-20, 1402/12/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of two fluid therapy methods with and without Lasix in crash injuries with lung contusion referred to Kerman Bahonar Hospital in 2023

Public title
Comparison of two fluid therapy methods with and without Lasix in crash injuries with lung contusion
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All adult patients (over 18 years old) with multiple trauma who were diagnosed with pulmonary contusion Having creatine kinase (CPK) values over 5000 U/L Non-invasive ventilation (NIV) due to hypoxia in the emergency department of Bahonar Hospital
Exclusion criteria:
Myocardial contusion Organ failure Chronic pulmonary disease Pulmonary embolism Need for massive transfusion Complications of of blood transfusion Spinal cord injury Acute kidney injury Not willing to participate in the study Death within the first 48 hours
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **28**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization method in such a way that blocks of size 4. Within each block, every position will be assigned to a number selected by the random numbers table, followed by defining the two positions with smaller numbers to the intervention and with the larger numbers to the control group. This process will be reversed in the next block.
Blinding (investigator's opinion)
Double blinded
Blinding description
This is a double blinded study in which people will be divided into two control and intervention groups. Participants and data analyzers will not be not aware of the allocation of the study groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee, Kerman University of Medical Sciences
Street address
Vice chancellor for research, Kerman University of Medical Science, Jahad street
City
Kerman
Province
Kerman
Postal code
7619813159
Approval date
2022-11-09, 1401/08/18
Ethics committee reference number
IR.KMU.AH.REC.1401.250

Health conditions studied

1

Description of health condition studied
Crush injuries
ICD-10 code
T14.7
ICD-10 code description
Crush injuries of unspecified body region

2

Description of health condition studied
Lung contusion
ICD-10 code
S27.32
ICD-10 code description
Contusion of lungs

Primary outcomes

1

Description
Systolic blood pressure
Timepoint
At the beginning of the study and every hour after treatment up to 48 hours
Method of measurement
Sphygmomanometer

2

Description
Diastolic blood pressure
Timepoint
At the beginning of the study and every hour after treatment up to 48 hours
Method of measurement
Sphygmomanometer

3

Description
Mean arterial pressure
Timepoint
At the beginning of the study and every hour after treatment up to 48 hours
Method of measurement
It is calculated based on diastolic and systolic blood pressure

4

Description
Pulse rate
Timepoint
At the beginning of the study and every hour after the initiation of treatment up to 48 hours
Method of measurement
Pulse oximeter

5

Description
Respiratory rate
Timepoint
At the beginning of the study and every hour after the initiation of treatment up to 48 hours
Method of measurement
Counting over a minute

6

Description
Arterial partial Pressure of Oxygen (PaO2)
Timepoint
At the beginning of the study and every hour after the initiation of treatment up to 48 hours
Method of measurement
Blood gas analyzer

7

Description
Serum sodium
Timepoint
At the beginning of the study and every 6 hours after the initiation of treatment up to 48 hours
Method of measurement
AutoAnalyzer

8

Description
Oxygen saturation (SaO2)
Timepoint
At the beginning of the study and every hour after the initiation of treatment up to 48 hours
Method of measurement
Pulse oximeter

9

Description
Creatine kinase
Timepoint
At the beginning of the study and every hour after the initiation of treatment up to 48 hours
Method of measurement
AutoAnalyzer

10

Description
Serum creatinine level
Timepoint
At the beginning of the study and every hour after the initiation of treatment up to 48 hours
Method of measurement
AutoAnalyzer

11

Description
Intake/output
Timepoint
At the beginning of the study and every 6 hours after the initiation of treatment up to 48 hours
Method of measurement
Intake /output chart

12

Description
PaO2/FiO2 ratio
Timepoint
At the beginning of the study and every 6 hours after the initiation of treatment up to 48 hours
Method of measurement
Ventilator settings and ABG results

13

Description
Intra-abdominal pressure
Timepoint
At the beginning of the study and every 6 hours after the initiation of treatment up to 48 hours
Method of measurement
Foley catheter attached to a manual manometer

Secondary outcomes

empty

Intervention groups

1

Description
Control group: Crystalloid infusion will be initiated for the patients as a one-liter bolus over 2 hours, followed by 6 liters per day until the patients be able to tolerate enteral feeding.
Category
Treatment - Other

2

Description
Intervention group: The volume and pace of infusion in this group will be the same as the control group. However, at the end of hour 3 after the initiation of fluid therapy, 40 mg of furosemide (20mg/2ml, Caspian Inc., IRAN) will be injected as a bolus which will be followed by an infusion of 2mg/hour by an infusion pump.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid bahonar hospital of kerman
Full name of responsible person
Mehdi Ahmadinejad
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Shahid bahonar hospital - Qorani St - Valiasr Crossroad
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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KMU_RESEARCH@YAHOO.COM
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
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
Ahmadinejad Mehdi
Position
Associate Professor - Fellow of Intensive Care
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
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Position

Associate Professor - Fellow of Intensive Care

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

Ahmadinejad Mehdi

Position

Associate Professor - Fellow of Intensive Care

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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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