

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 methods 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 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

+98 34 0223 5011

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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

Street address

Shahid bahonar hospital - Qorani St - Valiasr
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Dr. Reza Malekpour Afshar

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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

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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Person responsible for scientific inquiries

Contact

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Kerman University of Medical Sciences

Full name of responsible person

Ahmadinejad Mehdi

Position

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Full name of responsible person

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Position

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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