Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Aug 2026

A clinical trial of comparing the effect of Albumin administration on urine output when using with lasix and mannitol with using lasix and mannitol without Albumin in oliguric patients in ICU

Protocol summary

Summary

The main objective of this study is investigating the effect of Albumin on urine output, using it with lasix and mannitol in ICU patients with oliguria. This is a clinical trial on 100 patients in ICU who are suffering from acute renal failure and oliguria. Sampling will done using availability sampling method of patients in ICUs of Bahonar hospital of Kerman. Inclusion criteria: oliguric patients in ICU; patients with Acute Renal Failure. Exclusion criteria: history of kidney disorders (Cr>1.5mg/dl); proteinuria (urine pr>3.5g/d); kidney disorders like glomerulonephritis and ATN; consumption of furosemide within last two weeks; incorrect urine collection; urine line blockage; low level of albumin (below 4.5 mg/dl). The subjects are divided into two groups of intervention and control using simple randomization by means of draw. In intervention group in addition of lasix and mannitol, Albumin is administered. In control group just lasix and mannitol are given. Central venous Pressure, superficial edema and the ratio of PAO2/FIO2 will be measured before commerce of diuresis and during therapeutic period. Urine output is measured every 6 hours. BUN and Cr are measured at the time of admission and then daily. Glomerular filtration rate (GFR) is measured before commerce of diuresis and after starting diuresis. finally the collected data will be analyzed according to the study's objectives.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016013010741N3**
Registration date: **2016-04-28, 1395/02/09**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-04-28, 1395/02/09

Registrant information

Name
Minoo Ghahraman
Name of organization / entity
Kerman University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Kerman University of Medical Sciences

Expected recruitment start date

2015-04-21, 1394/02/01

Expected recruitment end date

2015-12-22, 1394/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial of comparing the effect of Albumin administration on urine output when using with lasix and mannitol with using lasix and mannitol without Albumin in oliguric patients in ICU

Public title

Investigating the effect of Albumin on urine output, using

it with lasix and mannitol in ICU patients with oliguria

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: oliguric patients in ICU; patients with Acute Renal Failure. Exclusion criteria: history of kidney disorders (Cr>1.5mg/dl); proteinuria (urine pr>3.5g/d); kidney disorders like glomerulonephritis and ATN; consumption of furosemide within last two weeks; incorrect urine collection; urine line blockage; low level of albumin (below 4.5 mg/dl).

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kerman University Medical Sciences

Street address

Kerman University Medical Sciences, Shafa Square

City

Kerman

Postal code

Approval date

2016-04-03, 1395/01/15

Ethics committee reference number

ir.kmu.rec.1394.710

Health conditions studied

1

Description of health condition studied

Acute renal failure

ICD-10 code

N17.9

ICD-10 code description

Acute renal failure, unspecified

Primary outcomes

1

Description

Serum BUN level

Timepoint

At the time of admission and then daily

Method of measurement

Blood test

2

Description

Serum Cr level

Timepoint

At the time of admission and then daily

Method of measurement

Blood test

Secondary outcomes

1

Description

Daily urine output

Timepoint

During hospital stay daily

Method of measurement

Documentation of collected urine in 24 hours

2

Description

Glomerular filtration rate (GFR)

Timepoint

Every day during hospital stay

Method of measurement

By means of creatinine clearance equation

3

Description

CVP

Timepoint

Before commerce of diuresis and during therapeutic period

Method of measurement

Monitoring device

4

Description

Superficial edema

Timepoint

Before commerce of diuresis and during therapeutic period

Method of measurement
Examination

Intervention groups

1

Description
In intervention group in addition to mannitol and lasix (400 mg lasix plus 100 ml mannitol 20% administering 1 mg/kg/h for 2 consecutive days), albumin (one vial of albumin 20% in 1 litre normal saline 2 times a day for 2 consecutive days) is given.
Category
Treatment - Drugs

2

Description
In control group mannitol and lasix (400 mg lasix plus 100 ml mannitol 20% administering 1 mg/kg/h for 2 consecutive days) is given.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Bahonar Hospital
Full name of responsible person
Mehdi Ahmadinejad
Street address
Bahonar Hospital, Bagh-e-melli square
City
Kerman

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Kerman University of Medical Sciences
Full name of responsible person
Fatemeh Hassani
Street address
Tahmasbabad Square, Ebnesina Street
City
Kerman
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Kerman University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Minoo Ghahraman
Position
Anesthesiologist
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty