Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jul 2026

Clinical evaluation of applying bio-impedance analysis as a guide to detect the appropriate ultrafiltration rate in patients undergoing continuous renal replacement therapy

Protocol summary

Study aim

Acute kidney injury (AKI) frequently occurs in intensive care units and increases the mortality rate, especially when the patients are over-hydrated. However, clinical and laboratory findings have poor sensitivity to detect volume overload in critically ill patients. There is no consensus about the way to determine appropriate ultrafiltration (UF) volume in patients on continuous renal replacement therapy (CRRT). In this study, we evaluate the benefits of fluid management based on bio-impedance analysis (BIA) in patients receiving CRRT.

Design

Randomized controlled trial, double blind, parallel group, single center

Settings and conduct

Participants are assigned to case and control groups by using a software generated table of random numbers. The results of bio-impedance-analysis are applied in management of patients in study group. Patients and outcome analyzer are blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Admission to the intensive care unit of Masih Daneshvari hospital and receiving CRRT for AKI Exclusion criteria: The age less than 18 years old Stage 4 or 5 of chronic kidney disease Kidney transplantation Limb amputation Cardiopulmonary resuscitation within 24 hours before CRRT Death during the first 24 hours of CRRT

Intervention groups

The body weights and compositions are measured by a bed scale and a BioScan-916 analyzer at the start of CRRT and every 8 hours thereafter. Hydration status was estimated by clinical findings in control group and the water content of lean body mass or the distance from the major axis of tolerance ellipse in bioimpedance vector analysis (BIVA) in study group. The UF rate was set and changed during CRRT based on the different protocols in each group.

Main outcome variables

Mortality rate Total volume removed during CRRT Hospital admission days Duration of staying in ICU Length of being under mechanical ventilation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181108041595N1**
Registration date: **2019-11-23, 1398/09/02**
Registration timing: **retrospective**

Last update: **2021-11-27, 1400/09/06**
Update count: **1**

Registration date

2019-11-23, 1398/09/02

Registrant information

Name

Farin Rashid Farokhi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2260 3282

Email address

f_rashid@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-19, 1397/01/30

Expected recruitment end date

2019-04-19, 1398/01/30

Actual recruitment start date
2018-04-19, 1397/01/30
Actual recruitment end date
2019-09-21, 1398/06/30
Trial completion date
2019-10-27, 1398/08/05

Scientific title
Clinical evaluation of applying bio-impedance analysis as a guide to detect the appropriate ultrafiltration rate in patients undergoing continuous renal replacement therapy

Public title
The effect of Bio-impedance Analysis in fluid management of patients on Continuous Renal Replacement Therapy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Admission to the intensive care units of Masih Daneshvari Hospital during the study period Occurring of acute kidney injury Requirement of continuous Renal Replacement Therapy Age of more than 18 years
Exclusion criteria:
History of of stage 4 and 5 of chronic kidney disease History of kidney transplantation Cardiorespiratory resuscitation within 24 hours before the start of Renal Replacement Therapy Patient death before 24 hours of starting first Continuous Renal Replacement Therapy History of limb amputation
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **65**
More than 1 sample in each individual
Number of samples in each individual: **1**
Each patients contribute one sample to the trial
Actual sample size reached: **65**
Randomization (investigator's opinion)
Randomized
Randomization description
All eligible patients admitted to the ICU during the study period are included. The method of randomization is simple and patients are assigned to case or control groups by using a software generated table of random numbers. Bio-impedance analysis is performed for all participant by the operator every 8 hours during performing CRRT. In order to carry out allocation concealment, the patient code is sent to a third party who has the table of random number to decide whether this code directs patient to the study or control group. Then he inform the principal investigator about the patient group. The investigator will apply the results of bio-impedance analysis in determining UF volume during CRRT only in case group.
Blinding (investigator's opinion)
Double blinded
Blinding description
Bio-impedance analysis is performed for all patients and our participants or their guardians are not awarded of the study group they are assigned to. Our data analyzer will analyze the data of two groups without having any other information about the aim of the study and case or control groups. In the study design, the results of bio-impedance analysis should be consider in the order of ultrafiltration volume is only in participants directed to study group. So, the main investigator can not be blinded.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Science
Street address
SBMU, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
19839-63113
Approval date
2018-04-17, 1397/01/28
Ethics committee reference number
IR.SBMU.MSP.REC.1397.102

Health conditions studied

1

Description of health condition studied
AKI- increase in serum creatinine by at least 0.3 mg/dl within 48 hours or 1.5 times baseline within prior 7 days or urine volume less than 0.5 ml/kg/hour for six hours
ICD-10 code
N17-N19
ICD-10 code description
Acute kidney failure

2

Description of health condition studied
Fluid overload:excess fluid in intracellular or extracellular compartments
ICD-10 code
E87.7
ICD-10 code description
Fluid overload

Primary outcomes

1

Description
The water content lean body mass
Timepoint
After 72 hours of undergoing CRRT with excluding the time in interruption periods between CRRT sessions
Method of measurement
Records of bioimpedance analyser instrument

Secondary outcomes

1

Description
Duration of ICU admission
Timepoint
After discharge from the hospital.
Method of measurement
Patient's medical files

2

Description
Duration of hospital admission
Timepoint
After discharge from the hospital.
Method of measurement
Patient's medical files

3

Description
time duration of spending under mechanical ventilation
Timepoint
After discharge from the hospital.
Method of measurement
Patient's medical files

4

Description
Urine output
Timepoint
every 8 hors during CRRT
Method of measurement
use of scaled containers

5

Description
Mortality rate
Timepoint
At 10th , 30th and 60th day of the study
Method of measurement
Patient are followed for mortality up to 60 days . At the 10th , 30th and 6th day , the mortality is recorded

Intervention groups

1

Description
Intervention group: In patients of this group the volume of fluid removal with ultrafiltration during CRRT is determined based on the results of bio-impedance analysis.
Category
Treatment - Devices

2

Description
Control group: In patients of this group the volume of fluid removal with ultrafiltration during CRRT is determined based on clinical findings.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Masih Daneshvari Hospital
Full name of responsible person
Farin Rashid Farokhi
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Daarabad ,Niavaran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Parissa Farnia

Street address
Masih Daneshvari Hospital, Darabad Avenue, Shahid Bahonar roundabout, Tehran, Iran
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Phone
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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Farin Rashid Farokhi
Position
Associate professor of nephrology
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
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Person responsible for scientific inquiries

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Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
Street address
5th west, 8, Ghobadian st., Alborz st., Mirdamad blv
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All individual non-identified participant data

When the data will become available and for how long

6 months after publication

To whom data/document is available

For people working in academic institutions

Under which criteria data/document could be used

Further sharing of the data should be with permission of original investigators The use of data for purposes other than those originally proposed in the application is prohibited

From where data/document is obtainable

The applicants can get the documents through the email, f_rashid@sbmu.ac.ir

What processes are involved for a request to access data/document

The process of evaluating the requests and sending these documents will take about 3 months.

Comments