

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)

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+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 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

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Tehran

Province

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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 hours 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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Parissa Farnia

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Masih Daneshvari Hospital, Darabad Avenue, Shahid
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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**Contact****Name of organization / entity**

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Position

Associate professor of Nephrology

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Latest degree

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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