

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Role of early hemodialysis on acute kidney injury in critically ill patients at Tehran Imam Khomeini Hospital

Protocol summary

Summary

Main purpose of the study : treatment (Role of early hemodialysis on acute kidney injury in critically ill patients) . Study design: interventional, non-randomized, double blind and parallel without placebo. Target sample size: 60 patients from both sexes between ages 18 and 60. If there is one of the following scales such as , at least 50% creatinine rise from the admission time , BUN>70, oliguria <0.5 ml/kg/h for 12 hours with no response to volume and Furosemide , anuria <0.3 ml/kg/h for 6 hours with no response to volume and Furosemide, will be specified as Early Hemodialysis Group (D) and if there is criteria such as volume overload (pulmonary edema) , BUN>100 or occurrence of azotemia complications (ex:loss of Consciousness) and cr>4 will be specified as Group C. In case of oliguria (U/O<0.5 ml/kg/h) or anuria (U/O<0.3 ml/kg/h or cessation of urine) , infusion of 500 ml crystalloid with 60 mg Furosemide in 1 hour will be administered and while there is no response , the patient entered the study. Exclusion criteria: history of renal insufficiency , reception of high dose inotropics, septic shock , severe electrolyte abnormalities leading to hemodialysis. Intervention: hemodialysis central vein catheter will be inserted for the patients and dialysis will start daily (2 hours for the first day then 4 hours). Dialysis will be done at least for 3 days and in case of appropriate urination , correction of urea or creatinine, dialysis implementation will be every other day for about 3 hours. When the blood urea and creatinine are stabled, the dialysis is suspended and restarting is according to mentioned indications. Primary outcome measure: plasma creatinine,blood urea and urine volume. Secondary outcome measure : length of stay and mortality rate in intensive care unit.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201507069045N3**

Registration date: **2016-04-03, 1395/01/15**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-04-03, 1395/01/15

Registrant information

Name

Mohammad Taghi Beigmohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6119 2511

Email address

beigmohammadi@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2016-02-20, 1394/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Role of early hemodialysis on acute kidney injury in critically ill patients at Tehran Imam Khomeini Hospital

Public title

Role of early hemodialysis on acute kidney injury in critically ill patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: if there is one of the following scales such as ; at least 50% creatinine rise from the admission time ; BUN>70 ; oliguria <0.5 ml/kg/h for 12 hours with no response to volume and Furosemide ; anuria <0.3 ml/kg/h for 6 hours with no response to volume and Furosemide; will be specified as Early Hemodialysis Group (D) and if there is criteria such as volume overload (pulmonary edema) ; BUN>100 or occurrence of azotemia complications (ex:loss of Consciousness) and cr>4 will be specified as Group C. In case of oliguria (U/O<0.5 ml/kg/h) or anuria (U/O<0.3 ml/kg/h or cessation of urine) , infusion of 500 ml crystalloid with 60 mg Furosemide in 1 hour will be administered and while there is no response , the patient entered the study; Exclusion criteria: history of renal insufficiency ; reception of high dose inotropics; septic shock ; severe electrolyte abnormalities leading to hemodialysis.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Not 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 Tehran University of Medical Sciences

Street address

Keshavarz Boulevard, Amir Abad, Tehran

City

Tehran

Postal code**Approval date**

2015-07-05, 1394/04/14

Ethics committee reference number

IR.TUMS.REC.1394.342

Health conditions studied**1****Description of health condition studied**

Acute renal injury

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Blood urea

Timepoint

Before intervention, daily after intervention

Method of measurement

Blood sample

2**Description**

Plasma creatinine

Timepoint

Before intervention, daily after intervention

Method of measurement

Blood sample

3**Description**

Urine volume

Timepoint

Before intervention, daily after intervention

Method of measurement

Fully catheter and urine bag

Secondary outcomes**1****Description**

Length of stay in intensive care unit

Timepoint

Daily

Method of measurement

Number of admission days in intensive care unit

2**Description**

Mortality rate in intensive care unit

Timepoint

Daily

Method of measurement

Rate of 28-day mortality

Intervention groups

1

Description

For early Hemodialysis Group (D) , central vein catheter will be inserted for the patients and dialysis will start daily (2 hours for the first day then 4 hours). Dialysis will be done at least for 3 days and in case of appropriate urination , correction of urea or creatinine, dialysis implementation will be every other day for about 3 hours. When the blood urea and creatinine are stabilized, the dialysis is suspended and restarting is according to mentioned indications. Solution for the hemodialysis: acidic hemodialysis concentrated 2.4920 ml. The solution must be diluted 35 times immediately before use. For this purpose ,add 1 liter of concentrated solution to 34 liter pure water. In case of turbid liquid or particles ,it is not usable. After use, the remaining solution must be discarded. Sodium bicarbonate will be added immediately before use. This solution contains: sodium chloride, potassium chloride, magnesium chloride, calcium chloride, glacial acetic acid, dextrose. Electrolytes are: sodium, potassium, magnesium, calcium, chloride, acetate. Maintenance condition: the solution must be away from light and kept under 30 c and protected from freezing. It is a product of Faran pharmaceutical chemical company, Tuyserkan, Iran.

Category

Treatment - Other

2

Description

Control group: in case of oliguria (U/O<0.5 ml/kg/h) or anuria (U/O<0.3 ml/kg/h or cessation of urine) , infusion of 500 ml crystalloid with 60 mg Furosemide in 1 hour will be administered and while there is no response , the patient entered the study and hemodialysis will started after inserting central vein catheter . Solution for the hemodialysis: acidic hemodialysis concentrated 2.4920 ml. The solution must be diluted 35 times immediately before use. For this purpose ,add 1 liter of concentrated solution to 34 liter pure water. In case of turbid liquid or particles ,it is not usable. After use, the remaining solution must be discarded. Sodium bicarbonate will be added immediately before use. This solution contains: sodium chloride, potassium chloride, magnesium chloride, calcium chloride, glacial acetic acid, dextrose. Electrolytes are: sodium, potassium, magnesium, calcium, chloride, acetate. Maintenance condition: the solution must be away from light and kept under 30 c and protected from freezing. It is a product of Faran pharmaceutical chemical company, Tuyserkan, Iran.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Intensive care units of Imam Khomeini Hospital

Full name of responsible person

Mohammad Taghi Beigmohammadi.MD

Street address

Imam Khomeini Hospital, Keshavarz Boulevard, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research , Tehran University of Medical Sciences

Full name of responsible person

Seyed Ahmad Rezaii

Street address

Keshavarz Boulevard , Amir Abad , Tehran

City

Tehran

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 , Tehran 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

Imam Khomeini Hospital Complex

Full name of responsible person

Mohammad Taghi Beigmohammadi.MD

Position

Head of Intensive Care Units

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

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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