

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 2026

### Clinical trial study of comparison of normal saline and lactated ringer for fluid therapy in emergency department of Imam Reza hospital

#### Protocol summary

##### Study aim

comparing hospitalization outcome (mortality and duration), renal function and perfusion status in patients receiving normal saline versus lactated ringer in the Emergency Department

##### Design

We will divide study period to consecutive three days clusters and allocate each cluster to one study group using random table. Code of fluid (instead of name of fluid) will be written on pocket label. Just drug provider knows code of each fluid.

##### Settings and conduct

Emergency Department of Imam Reza Hospital at Kermanshah

##### Participants/Inclusion and exclusion criteria

every patient in the acute emergency ward that will receive fluid and -there isn't any contraindication to one of each fluids and -is not need to specific serum and -is not need to receive any drug that has interaction with these fluids

##### Intervention groups

first group who receive normal saline and second group receive lactated ringer at the emergency department

##### Main outcome variables

in hospital mortality and hospitalization days, renal function, serum concentration of hydrogen ion, lactate, potassium, and chloride, 6 and 24 hours after fluid initiation

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20181105041562N1**

Registration date: **2018-11-19, 1397/08/28**

Registration timing: **prospective**

Last update: **2018-11-19, 1397/08/28**

Update count: **0**

##### Registration date

2018-11-19, 1397/08/28

##### Registrant information

###### Name

Ali Aliee

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 83 3825 2948

###### Email address

ali.aliee@kums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-12-22, 1397/10/01

##### Expected recruitment end date

2019-03-20, 1397/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Clinical trial study of comparison of normal saline and lactated ringer for fluid therapy in emergency department of Imam Reza hospital

##### Public title

comparing crystalloids

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

all patients of emergency department that fluid prescribed for them age more than 14

**Exclusion criteria:**

contraindication to each of these two fluids (according to FDA guideline) need to another fluid for patient need to infusion of drugs that can't infused with one of these fluids

**Age**

From **15 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **1300**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

each cluster will be defined as patients of 3 consequent days. clusters will allocate to each group using random number table. the person who is responsible for providing drugs will have allocation list of clusters.

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

there is code of fluid (instead of name of fluid) on fluid pocket labels. Just drug providers knows the code of fluid.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Ethics committee of Kermanshah University of Medical Sciences

**Street address**

building No2, Kermanshah University of Medical Sciences, Beheshti Blvd, Kermanshah, Iran

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6714638381

**Approval date**

2018-09-11, 1397/06/20

**Ethics committee reference number**

IR.KUMS.REC.1397.574

**Health conditions studied**

**1**

**Description of health condition studied**

patients of emergency department of general hospitals that receive intravenous fluid

**ICD-10 code**

E86.0

**ICD-10 code description**

Dehydration

**Primary outcomes**

**1**

**Description**

in hospital death

**Timepoint**

discharge time

**Method of measurement**

based on hospital record

**2**

**Description**

duration of hospitalization

**Timepoint**

at the end of hospitalization

**Method of measurement**

based on hospital record

**3**

**Description**

creatinine clearance

**Timepoint**

6 and 24 hours after initiation of IV fluid

**Method of measurement**

creatinine clearance estimated by the Cockcroft-Gault equation

**Secondary outcomes**

empty

**Intervention groups**

**1**

**Description**

Intervention group: Normal Saline group: patients in this group receive normal saline. volume and speed of fluid will be prescribed by responsible physician that is not dependent of type of crystalloid. name of patient and time of infusion will be recorded on fluid pocket label by

nurse. observer will assess all pockets after usage about volume and time of infusion and will record it.

**Category**

Treatment - Drugs

**2****Description**

Intervention group: Lactated Ringer group: patients in this group receive normal saline. volume and speed of fluid will be prescribed by responsible physician that is not dependent of type of crystalloid. name of patient and time of infusion will be recorded on fluid pocket label by nurse. observer will assess all pockets after usage about volume and time of infusion and will record it.

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Imam Reza hospital

**Full name of responsible person**

Ali Aliee

**Street address**

end of Parastar Blvd, Kermanshah, Iran

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kermanshah

**Province**

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**Postal code**

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**Phone**

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**Fax**

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**Email**

ali.aliee@kums.ac.ir

**Web page address**

<http://imamreza.kums.ac.ir/>

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Farid Najafi

**Street address**

building No 2, Kermanshah University of Medical Sciences, Beheshti Blvd

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Kermanshah

**Province**

Kermanshah

**Postal code**

6715847141

**Phone**

+98 83 3837 0541

**Fax**

+98 83 3838 6835

**Email**

farid\_n32@yahoo.om

**Web page address**

<http://vc-research.kums.ac.ir/>

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Kermanshah 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**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Ali Aliee

**Position**

resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Emergency Medicine

**Street address**

Unit 8, Arian Building, No 65, Hajdayi alley, Golestan, Kermanshah, Iran

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

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resident

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alialiee@gmail.com

**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