Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jul 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 crystaloids

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 crystaloid. 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 crystaloid. 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

City

kermanshah

Province

Kermanshah

Postal code

6742775333

Phone

+98 83 3427 6301

Fax

+98 83 3427 6300

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

City

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

City

kermanshah

Province

Kermanshah

Postal code

6714638381

Phone

+98 83 3825 2948

Email

alialiee@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Ali Aliee

Position
resident
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Other areas of specialty/work
Emergency Medicine
Street address
Unit 8, Arian Building, No 65, Hajdayi alley, Golestan, Kermanshah, Iran
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kermanshah
Province
Kermanshah
Postal code
6714638381
Phone
+98 83 3825 2948
Email
alialiee@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Kermanshah University of Medical Sciences
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Ali Aliee
Position
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Emergency Medicine
Street address
Unit 8, Arian Building, No 65, Hajdayi alley, Golestan, Kermanshah, Iran
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6714638381
Phone
+98 83 3825 2948
Email
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