

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effect of maintenance serum with the amount of sodium at the limit of isotonic saline on sodium level, blood pressure and acidosis in PICU patients of Tehran Bahrami Children's Hospital

Protocol summary

Study aim

Determination of sodium level, blood pressure and acidosis in patients receiving serum with sodium level equal to isotonic saline

Design

This double-blind clinical trial study was conducted in the PICU department of Bahrami Children's Hospital in Tehran in 1401. 90 eligible children were admitted to the PICU department and were assigned to two normal and half-saline groups one by one and based on the Block Random Allocation software with variable sizes multiples of 2.

Settings and conduct

When a patient is admitted to the pediatric intensive care unit, the nurse informs the investigator. He/she chooses one pocket if the patient is recruited. The investigator evaluates the variables from sheets completed by the caregiver team. Uncoding is done after data collection and analysis.

Participants/Inclusion and exclusion criteria

It includes children between the ages of 3 months and 18 years who are hospitalized and need intravenous serum. And the exclusion conditions include kidney patients and electrolyte disorders.

Intervention groups

The intervention group receives normal saline and the control one receives half saline. The fluid volume and rate are calculated based on weight and are the same in both groups. No other interventions were undertaken on other fluid requirements, drugs, etc.

Main outcome variables

Blood Sodium level; blood pressure; blood acidosis and bicarbonate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230414057904N1**

Registration date: **2024-01-10, 1402/10/20**

Registration timing: **retrospective**

Last update: **2024-01-10, 1402/10/20**

Update count: **0**

Registration date

2024-01-10, 1402/10/20

Registrant information

Name

Faezeh Jahanshahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2244 2920

Email address

faezehjahanshahi3@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-25, 1401/01/05

Expected recruitment end date

2023-02-04, 1401/11/15

Actual recruitment start date

2022-03-25, 1401/01/05

Actual recruitment end date

2023-02-04, 1401/11/15

Trial completion date

2023-02-07, 1401/11/18

Scientific title

Evaluation of the effect of maintenance serum with the

amount of sodium at the limit of isotonic saline on sodium level, blood pressure and acidosis in PICU patients of Tehran Bahrami Children's Hospital

Public title

Evaluation of the effect of maintenance serum with the amount of sodium at the limit of isotonic saline on sodium level, blood pressure and acidosis in admitted patients.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 3 months and 18 years Need for injectable serum

Exclusion criteria:

Sodium level below 130 mmol/L Sodium level above 150 mmol/L Having diabetes insipidus Diabetic ketoacidosis Kidney disease requiring dialysis Suffering from the disease of high sodium urinary excretion(Addison's disease, congenital adrenal hyperplasia, Barrett's syndrome) Patients before or after neurosurgery Require chemotherapy hydration Severe liver disease Patients who are likely to receive maintenance serum for less than 6 hours

Age

From **3 months** old to **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **90**

Actual sample size reached: **88**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are assigned to normal and half-saline groups, one by one, and based on the Block Random Allocation software with variable sizes multiples of 2.

Randomization in two strata will be done separately. We write every code on paper and put it in a pocket which its content cannot be read. Every code is allocated to every patient who is included until the end.

Blinding (investigator's opinion)

Double blinded

Blinding description

The legal guardian and/or the patient is aware of participating in the study but, does not know the fluid types. The care provider and the nurse who are not a research member know the fluid type but, the investigator, outcome assessor, and data analyzer do not.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mohammad Eftekhari

Street address

Keshavarz Blvd, Tehran university of medical science, school of medicine, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

+98-21

Approval date

2021-10-11, 1400/07/19

Ethics committee reference number

IR.TUMS.CHMC.REC.1400.145

Health conditions studied

1

Description of health condition studied

Hypertension

ICD-10 code

I15.8

ICD-10 code description

Other secondary hypertension

2

Description of health condition studied

Influence of the maintenance fluid (normal vs. half saline) on blood sodium level

ICD-10 code

E87.1

ICD-10 code description

Hypo-osmolality and hyponatremia

Primary outcomes

1

Description

Blood Sodium level

Timepoint

6,24,48, and 72 hours

Method of measurement

Blood lab test, with the same kit for all patients.

2

Description

Blood pressure

Timepoint

Every hour

Method of measurement

Non-invasive blood pressure monitoring, with appropriate cuff size

3

Description

Blood PH

Timepoint

hours 6, 24, 48 , 72

Method of measurement

Blood lab test, with the same kit for all patients.

4

Description

Blood bicarbonate level

Timepoint

hours 6, 24, 48 , 72

Method of measurement

Blood lab test, with the same kit for all patients.

Secondary outcomes

empty

Intervention groups

1

Description

Normal saline maintenance fluid, 4cc/kg.h for first 10kg, 2cc/kg.h for second 10kg, and 2cc/kg.h for third and more 10kg. There is no specific brand to use and it will depend on Bahrami hospital's drugstore. Training sessions is not in our method. Administration time will depend on ICU admission period. The chemical formula is obvious according to drug's name and it is NaCl 0.9%.

Category

Treatment - Other

2

Description

Control group: Half saline maintenance fluid, 4cc/kg.h for first 10kg, 2cc/kg.h for second 10kg, and 2cc/kg.h for third and more 10kg. There is no specific brand to use and it will depend on Bahrami hospital's drugstore. Training sessions is not in our method. Administration time will depend on ICU admission period. The chemical formula is obvious according to drug's name and it is NaCl 0.45%.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Bahrami Children's Hospital

Full name of responsible person

Faezeh Jahanshahi

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Damavand St., Kiaei St., Ansar Al Hossein St

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Web page address

<https://bahrami.tums.ac.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Vice Chancellor for Research

Street address

Enghelab st, Qods st, Poursina st, school of medicine

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1461884513

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Web page address

<https://Bahrami.tums.ac.ir>

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran 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

Web page address
<https://bahrami.tums.ac.ir>

Person responsible for general inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Faezeh Jahanshahi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Pediatrics
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The information related to the questionnaire, which includes the individual characteristics of the participants and the variables and outcomes, will be shared.

When the data will become available and for how long

The access period starts from 1402

To whom data/document is available

Study documents will be accessible to study reviewers and researchers of academic and scientific centers. بر

Under which criteria data/document could be used

The study documents will be accessible to the reviewers

of the project for the purpose of verification without conditions. It will be useful for others (researchers working in academic and scientific institutions) in order to improve the quality of treatment in childrens filed with respect to trustworthiness standards.

From where data/document is obtainable

Applicants can request the study documents from the researcher through the postal address and e-mail, and they can also interact in person. Email : faezehjahanshahi3@gmail.com Postal code :

1955673933 Address : No. 29,. Sabouri St,. Alborz St., Naft Town,. Artesh Sharq Highway., Imam Ali Highway., Tehran

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

The study documents will be sent to the email address after the request which should be from an ethical committee or reference and with the supervisor professor's permission.

Comments