

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the Effects of intravenous fluid with different concentrations of sodium on serum sodium levels in patients admitted to the intensive care unit of Bahrami Children's Hospital in 2012-13.

Protocol summary

Summary

Traditionally, maintenance fluid replacement in children about 50 years ago based on Holliday Segar liquid formula Hypotonic used. In recent years, studies have shown that the use of Hypothonic liquid can Hyponatremia some children due to fluid therapy. In some cases, Hyponatremia can lead to irreversible neurological symptoms and even death. Hypothonic (serum containing 30 meq/lit in children under 12 months, containing 50 meq/lit children over 12 months) with intravenous fluid contains high levels of sodium (serum containing 50 meq/lit in children under 12 months and children over 12 months liquid 100meq.lit), on admission and 24 hours after starting rehydration, compared to volume urine in children receiving intravenous fluid Hypothonic with intravenous fluid contains high levels of sodium, on admission and 24 hours after starting rehydration compared blood pressure changes in children receiving intravenous fluid Hypothonic with intravenous fluid contains high levels of sodium, on admission and 24 hours after starting rehydration compared the prevalence of hypernatremia , Hyponatremia (serum sodium level greater than 135 - 145) in both fluids. Inclusion criteria: children in age from 30 days to 14 years without speaking to him prescribe intravenous fluid for at least 24 hours in the ICU Bahrami Children Hospital, Tehran University of Medical users are admitted. Exclusion criteria: patients with acute or chronic renal parenchymal; patients at risk of cerebral edema; diabetic ketoacidosis; head trauma; heart disease; patients Hypoglycemia; patients with abnormal secretion of antidiuretic hormone; diabetes insipidus disorders; pituitary or hypothalamic; patients underwent surgery to have lost a lot of blood during surgery; patients after surgery of cranial or thorax; cirrhotic patients; patients with severe malnutrition; diabetes; any disease that his doctors do not accept this

fluid. Withdrawal criteria: children with higher serum sodium lower than the normal range (135_145); would be required CPR; intubation; death, early oral feeding, any conditions that the patient's physician his decision to withdraw from the study or decide to change intravenous fluids. In the beginning especially sodium levels, blood pressure and urine specific gravity will be check and again 24 hours after initiation of intravenous fluid to be re- check. Liquid sodium 50 and 100 mEq per liter of liquid will be used. Fluid besides sodium respectively containing potassium of 20 mEq per liter of liquid glucose to a concentration of 10 grams per liter. Fluid volume shall be calculated according to the formula Holliday _ segar , so go for one weighing 10 kg and 10 kg weight Kg 100 cc per second per Kg weight of 50 cc and 20 cc per kg body weight remaining Kg weight may be given intravenous fluid every 24 hours . Finally, the groups are compared in terms of average plasma sodium. The specific gravity of the urine and blood pressure before and after receiving IV therapy is evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013121015740N1**

Registration date: **2014-05-04, 1393/02/14**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-05-04, 1393/02/14

Registrant information

Name

Motahare Aghajani Delavar

Name of organization / entity

Tehran Univercity Of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source
Investigator

Expected recruitment start date
2012-12-30, 1391/10/10

Expected recruitment end date
2014-01-04, 1392/10/14

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the Effects of intravenous fluid with different concentrations of sodium on serum sodium levels in patients admitted to the intensive care unit of Bahrami Children's Hospital in 2012-13.

Public title
Effect of intravenous fluid sodium concentration on plasma sodium in pediatric patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: children in the age range 30 days to 14 years for his doctor prescribe intravenous fluid and pain for at least 24 hours in hospital pediatric intensive care Bahrami, Tehran University of Medical are admitted users. Exclusion criteria: patients with acute or chronic renal parenchymal problems, such as diabetic ketoacidosis and cerebral edema in patients at risk of trauma to the head, heart disease; hypoglycemic patients; patients with abnormal secretion of antidiuretic hormone; diabetes insipidus; pituitary or hypothalamic disorders. patients underwent surgery to have lost a lot of blood during surgery, and cranial thoracic surgery patients; cirrhotic patients; patients with severe malnutrition; diabetes, and his doctor to his patient fluid therapy in a framework designed this study can not reject. Withdrawal criteria; The research indicates that children with higher serum sodium lower than the normal range (135_145); the need to take CPR; being intubated; the death; early oral feeding; or any condition that a doctor's decision to withdraw his case if the study or decide to change intravenous fluids may be excluded.

Age
From **1 year** old to **14 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
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

Medical Ethics Committee of Tehran University of Medical Sciences

Street address

Keshavarz st.Ghods st.

City

Tehran

Postal code

Approval date

2012-05-21, 1391/03/01

Ethics committee reference number

3480/13091/5

Health conditions studied

1

Description of health condition studied

Hyponatremia

ICD-10 code

E87.1

ICD-10 code description

Hypo-osmolality and Hyponatremia

Primary outcomes

1

Description

Plasma concentrations of sodium

Timepoint

24 hours after initiation of intravenous fluid

Method of measurement

Sodium concentration in the blood sample

Secondary outcomes

1

Description

Complications Haypvnatrmty

Timepoint

During and after reading

Method of measurement

Clinical interviews with hospital doctors

Intervention groups

1

Description

In the intervention group, in children over 1, the maintenance intravenous fluid with the common volume and calculated based on the Holliday-Segar formula containing 100 MEq of sodium per liter has been used and in children under 1, 50 MEq of sodium has been used. In addition to sodium, the intravenous fluid contains potassium at 20 MEq per one liter of fluid and glucose with a concentration of 10 g/L, respectively. The volume of the received fluid will be calculated based on the Holliday-segar formula; thus, for the first 10 kilograms, 100 cc weigh per kilogram of weight and for the second 10 kilogram, 50 cc per kilogram weight and for the rest of the weight, 20 cc per kilogram weight of the intravenous fluid are prescribed during 24 hours.

Category

Treatment - Other

2

Description

In the control group, in children over 1 years old the maintenance intravenous fluid with the common volume and calculated through the Holliday-Segar formula containing 50 MEq of sodium per liter has been used and in children under 1 years old, 30 MEq of sodium has been used. In addition to sodium, the intravenous fluid contains potassium at 20 MEq per one liter of fluid and glucose with a concentration of 10 g/L, respectively. The volume of the received fluid will be calculated based on the Holliday-segar formula; thus, for the first 10 kilograms, 100 cc weigh per kilogram of weight and for the second 10 kilogram, 50 cc per kilogram weight and for the rest of the weight, 20 cc per kilogram weight of the intravenous fluid are prescribed during 24 hours.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Bahrami Children's Hospital

Full name of responsible person

Dr. Motahare Aghajani Delavar

Street address

Ghasem abad st. Shahid kiaei

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tehran University of Medical Sciences

Full name of responsible person

Dr. Masood Yunesian

Street address

Keshavarz st, Ghods st

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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

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

Tehran University of Medical Sciences

Full name of responsible person

Dr. Motahare Aghajani Delavar

Position

Resident of Pediatrics

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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