

Which intravenous fluid should be given for hospitalized patients?: A prospective randomised study

Submission date
14/05/2007

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
28/09/2007

Overall study status
Completed

☐ Statistical analysis plan

☐ Results

Last Edited
10/03/2008

Condition category
Nutritional, Metabolic, Endocrine

☐ Individual participant data

☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

Study objectives

The hypothesize of the study is that in sick children, moderately hypotonic fluids (such as fluids contain 77 mmol/L sodium) are better tolerated (i.e. induce less hyponatraemia without the risk of hypernatraemia) than conventional intravenous fluids that contain 34 mmol/L sodium.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethical Board of Istanbul University, Istanbul Faculty of Medicine, approved on 13 June 2005.
Ref: 2005/526.

Study design

Randomized controlled trial.

Primary study design

Interventional

Study type(s)

Not Specified

Health condition(s) or problem(s) studied

Hyponatraemia

Interventions

The patients were randomized to one of the three study arms prospectively. Stratified block randomization was performed, with each one-week block featuring a different intravenous solution. Randomization was performed separately for children on the ward and children in the Paediatric Intensive Care Unit (PICU).

Arm 1: 0.2% sodium in 5% dextrose

Arm 2: 0.3% sodium in 3.3% dextrose

Arm 3: 0.45% sodium in 5% dextrose

When hyponatraemia developed in any group during the therapy intravenous fluid sodium composition was increased and fluid therapy was decreased to 80% of the initial volume.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Intravenous Fluid

Primary outcome(s)

Association between administration of hypotonic fluids and hospital-acquired hyponatraemia, assessed by the following:

1. Plasma sodium, potassium and osmolality in all blood samples collected at admission (T0) and 12 (T12), 24 (T24), 48 (T48) and 72 (T72) hours of intravenous fluids therapy
2. Plasma urea, creatinine and uric acid, measured in all blood samples collected at T0 and T24

Key secondary outcome(s)

To determine contributive factors that may increase hyponatraemia risk, assessed by the following:

1. Plasma sodium, potassium and osmolality in all blood samples collected at admission (T0) and 12 (T12), 24 (T24), 48 (T48) and 72 (T72) hours of intravenous fluids therapy.
2. Plasma urea, creatinine and uric acid, measured in all blood samples collected at T0 and T24.
3. Plasma AntiDiuretic Hormone (ADH), measured at T0. Abnormal ADH function was assessed by serum osmolality and serum sodium determinations.

Completion date

26/05/2006

Eligibility

Key inclusion criteria

All children aged between 3 months to 16 years old who received intravenous fluids

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

3 months

Upper age limit

16 years

Sex

Not Specified

Key exclusion criteria

1. Dehydration
2. Cerebral oedema
3. Nephrotic syndrome
4. Hepatorenal syndrome
5. Plasma sodium level below 135 mmol/L
6. Congestive heart failure
7. Renal failure
8. Inborn error of metabolism

- 9. Protein energy malnutrition
- 10. Patients receiving mannitol or diuretics
- 11. Patients whose fluid therapy was started before admission

Date of first enrolment

15/06/2005

Date of final enrolment

26/05/2006

Locations

Countries of recruitment

Türkiye

Study participating centre

Istanbul University

Istanbul

Türkiye

34390

Sponsor information

Organisation

Istanbul University, Faculty of Medicine (Turkey)

ROR

<https://ror.org/03a5qrr21>

Funder(s)

Funder type

Other

Funder Name

Mainly investigator-funded with support from Ege Medical Company (Turkey)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration