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

Submission date	Recruitment status	[ ] Prospectively registered
14/05/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
28/09/2007	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
10/03/2008	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Not Specified

Participant information sheet

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 measure
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

Secondary outcome measures
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.

Overall study start date
15/06/2005

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

Age group
Child

Lower age limit
3 Months

Upper age limit
16 Years

Sex
Not Specified

Target number of participants
100

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)

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Sponsor type
University/education

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration