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Estimation of safe post-operative fluid therapy in children

Submission date 25/02/2011	**Recruitment status** Stopped	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data [_] Record updated in last year
Registration date 17/03/2011	**Overall study status** Stopped	
Last Edited 09/07/2020	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Rafael Krmar

Contact details
Department of Pediatrics
Karolinska University Hospital, Huddinge
S-141 86 Stockholm
Stockholm
Sweden
S-141 86
-
rafael.krmar@ki.se

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Clinical Trial register database registry number (http://www.kctr.se): CT20110060

Study information

Scientific Title
The efficacy of hypotonic and near-isotonic saline for parenteral fluid therapy given at low maintenance rate in preventing significant change in plasma sodium in post-operative paediatric patients: a prospective randomised non-blinded study

Study objectives
Hyponatremia is the most frequent electrolyte abnormality observed in post-operative paediatric patients receiving intravenous maintenance fluid therapy. If plasma sodium concentration (p-Na+) declines to levels below 125 mmol/L in < 48 h, transient or permanent brain damage may occur.

There is an intense debate as to whether the administered volume (full rate vs. restricted rate of infusion) and the composition of solutions used for parenteral maintenance fluid therapy (hypotonic vs. isotonic solutions) contribute to the development of hyponatremia. Lines of evidence indicates that post-operative hyponatremia would be the result of dilution of body solutes, i.e. an excess of water in relation to the existing sodium stores rather than to an increase in urinary sodium excretion. This phenomenon might occur whenever antidiuretic hormone levels are increased, like in clinical conditions such as surgery.

Our hypothesis is that regardless of the parenteral fluid therapy to be administered, on the condition that the patients extracellular fluid compartment is preserved and the urinary dilution capacity is suspected to be impaired by non-osmotic stimulated antidiuretic hormone activity, hyponatremia will not develop if fluid therapy is given at low maintenance rate i.e. approximately 3/4 of the average maintenance allowance.

Please note that as of 20/06/2011 the anticipated start and end dates of this trial have been updated. The previous dates were as follows:
Previous anticipated start date: 04/07/2011
Previous anticipated end date: 03/12/2012

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study protocol has been approved by the Medical Ethics Committee at Karolinska University Hospital, Stockholm, Sweden on 1st November 2010, Protocol No. 2010/2:9

Study design
Prospective randomised non-blinded study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Emergency intervention for treatment of acute appendicitis in children and adolescents

Interventions
As of 19/04/2012 the status of this record was changed to 'stopped' due to low patient recruitment rate. The trial officially stopped on 18/04/2012.

Eligible patients will be randomly assigned to receive one of the following :
Eelectrolyte/glucose combinations as parenteral maintenance fluid therapies during the 24 h following surgery:
1. 0.23% sodium chloride (40 mmol/L Na+ + 20 mmol/L K+ + 60 mmol/L Cl-; extempore solution) in 5% glucose
2. 0.40% sodium chloride (70 mmol/L Na+ + 45 mmol/L Cl- + 25 mmol/L acetate; B. Braun Melsungen AG, Melsungen, Germany) in 2.5% glucose
3. 0.81% sodium chloride (140 mmol/L Na+ + 4 mmol/L K+ + 1 mmol/L Ca2+ + 1 mmol/L Mg2+ + 118 mmol/L Cl- + 30 mmol/L acetate; Serumwerk Bernburg AG, Bernburg, Germany) in 1% glucose (the chemical symbols K+, Cl-, Ca2+, and Mg2+ refer to potassium, chloride, calcium, and magnesium, respectively)

The fluid needs for parenteral therapy will be estimated based on metabolic requirements of the body, i.e. expenditure of energy, as described by Holliday and Segar where daily caloric expenditure is equal to 100 cal/kg BW up to 10 kg, 1000 cal + 50 cal/kg BW from 11 to 20 kg and 1500 cal + 20 cal/kg BW over 20 kg. Since prescription of intravenous fluid therapy given at full maintenance rate may be potentially dangerous when renal water excretion is limited by excess antidiuretic hormone, parenteral fluid therapy will be given at a lower rate than the recommended average maintenance rate. In accordance with our local care guidelines for parenteral fluid therapy following surgical procedures, approximately 3/4 of the average maintenance allowance, percentage of the average maintenance rate will be prescribed to all participants for the first 24 h post-operatively.

For further information regarding sample size calculation, which is based on an hypothetical condition, please contact rafael.krmar@ki.se

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
To evaluate whether the post-operative prescription of either hypotonic (0.23% and 0.40% sodium chloride) or near-isotonic (0.81% sodium chloride) fluid therapy given at low maintenance rate in otherwise healthy children with normal post-operative p-Na+ are equally effective in maintaining p-Na+ within the normal range 24 h postoperatively

Secondary outcome measures
To determine water and electrolyte-balance during the administration of the investigational parenteral maintenance fluids as well as to investigate known regulatory hormones involved in the homeostatic control of water balance. We will also seek to determine how frequently p-Na+ should be monitored during the 24 h post-operative period.

Overall study start date
01/11/2011

Completion date
01/11/2012

Reason abandoned (if study stopped)
Prematurely stopped due to a low patient recruitment rate

Eligibility

Key inclusion criteria
1. Male and female children and adolescents aged between 1 and 14 years old whose post-operative p-Na+ are within the normal range (local reference range: 135 147 mmol/L)
2. Children and adolescents undergoing emergency intervention for treatment of acute appendicitis either as an open or laparoscopic procedure will be considered to be potentially eligible
To qualify for randomisation, the participants are required to have a complicated appendicitis, i. e. gangrenous or perforated, either with generalised or localised peritonitis of such a degree that the surgeon considers oral feeding unsuitable for at least 24 hours following the surgery. Consequently, the randomisation will be performed post-operatively and on the basis of intra-operative findings.

We infer that in our study population, the prescription of parenteral fluid therapy for the immediate 24 hours post-operative period might be justified and that by delaying oral fluid therapy intake, in any particular case, will do no harm to the patient.

Participant type(s)
Patient

Age group
Child

Lower age limit
1 Years

Upper age limit
14 Years

Sex
Both

Target number of participants

The number of patients per study arm needed to fulfill the power goal of the study will be 17 patients.

Key exclusion criteria
1. Any clinical condition, such as renal disease, acute or chronic lung inflammation, pituitary or hypothalamic disease and adrenal insufficiency that eventually can lead to electrolyte and water imbalance
2. Any patient whose p-Na+ is < 130 mmol/L after the initiation of parenteral maintenance fluid therapy, will be withdrawn from the study and treated accordingly at the discretion of the anaesthesiologist responsible for the patients care

Date of first enrolment
01/11/2011

Date of final enrolment
01/11/2012

Locations

Countries of recruitment
Sweden

Study participating centre
Department of Pediatrics
Stockholm
Sweden
S-141 86

Sponsor information

Organisation
Karolinska University Hospital (Sweden)

Sponsor details
Department of Pediatric Anesthesia and Intensive Care, ALB, Karolinska University Hospital, Solna.
Stockholm
Sweden
S-171 76

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00m8d6786

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded (Sweden)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	05/07/2011		Yes	No
Results article	results	01/07/2019	09/07/2020	Yes	No