

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Evaluation of postoperative hyponatremia in patients admitted in urology ward with two different intravenous fluids.

Protocol summary

Summary

English Abstract Objectives: Investigating the development of hyponatremia after administration of hypotonic (1/3-2/3) or isotonic (normal saline) maintenance intravenous fluid in children hospitalized in urology ward and undergone surgical operations. Total number of patients are 150 and any child admitted in urology ward undergoing surgery is included in this study. Methods: Randomized control study is conducted in Children Medical Center Hospital of Tehran, Iran. The prevalence of hyponatremia before and 6 hours after finishing of surgery will be determined in both groups. Other characteristics of the patients such as age, gender, duration of hospitalization, other concomitant electrolyte disturbances and symptoms pertaining to hypervolemia are also considered. The incidence of intravenous fluid therapy induced hyponatremia will be analyzed in different categories of patients. Those with underlying renal problems, liver diseases, cardiac problems, neurogenic bladder, diabetes melitus and diabetes insipidous are excluded from study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014122720448N1**

Registration date: **2015-06-23, 1394/04/02**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-06-23, 1394/04/02

Registrant information

Name

Mastaneh Moghtaderi

Name of organization / entity

Tehran University of Medical Science, Children Medical Center Hospital

Country

Iran (Islamic Republic of)

Phone

+98 21 6694 5580

Email address

drmoghtaderi@gmail.com

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2015-04-04, 1394/01/15

Expected recruitment end date

2015-06-21, 1394/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of postoperative hyponatremia in patients admitted in urology ward with two different intravenous fluids.

Public title

Evaluation of postoperative hyponatremia in patients admitted in urology ward with two different intravenous fluids.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Admission in urology ward and undergoing surgery Exclusion criteria: underlying renal disease ; liver disease ; cardiac problems ; neurogenic bladder ; diabetes melitus ; diabetes incipidous

Age

From **1 month** old to **14 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **150**

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**

Tehran University of Medical Sciences

Street address

Keshavarz Blvd. Ghods Corner

City

Tehran

Postal code**Approval date**

2015-02-17, 1393/11/28

Ethics committee reference number

93-03-184-27280-135489

Health conditions studied**1****Description of health condition studied**

Hyponatremia

ICD-10 code

E87.1

ICD-10 code description

Hypo-osmolality and hyponatraemia

Primary outcomes**1****Description**

Na level of serum after surgery

Timepoint

before and after surgery

Method of measurement

blood sample assay

Secondary outcomes**1****Description**

Clinical signs of hyponatremia

Timepoint

pre and post surgery state

Method of measurement

evaluation of serum Na

Intervention groups**1****Description**

In the first group like previous after checking serum level of Na we give them 1/3 - 2/3 fluid therapy and six hours after surgery we control serum Na level again to assess hyponatremia incidence.

Category

Treatment - Drugs

2**Description**

In the second group like others after checking serum level of Na we give them normal saline serum therapy and six hours after surgery we control serum Na level again to assess hyponatremia incidence in this group.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Children Medical Center Hospital

Full name of responsible person

Dr. Mastaneh Moghtaderi

Street address

Gharib street

City

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Dr. Masood Yunesian

Street address

Keshavarz Blvd, Ghods Corner

City

Tehran

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

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

Children Medical Ccenter Hospital

Full name of responsible person

Dr. Mastaneh Moghtaderi

Position

Pediatric Nephrologist

Other areas of specialty/work

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Person responsible for scientific inquiries

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Children Medical Center Hhospital

Full name of responsible person

Dr. Mastaneh Moghtaderi

Position

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Person responsible for updating data

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Name of organization / entity

Children Mmedical Center Hospital

Full name of responsible person

Dr. Mastaneh Moghtaderi

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Web page address

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