

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Evaluation of the effect of using two methods of fluid therapy with normal saline and one-fifth-four-fifth serum on plasma sodium and plasma glucose levels during and after neonatal surgery

Protocol summary

Study aim

Determining the effect of using two methods of fluid therapy with normal saline serum or one-fifth-four-fifth serum on plasma sodium and blood sugar levels during and after neonatal surgery

Design

Clinical trial without control group, with parallel, randomized groups

Settings and conduct

The present three-blind clinical trial study is performed on 72 1 to 30 day old infants in Imam Hossein Hospital, candidates for general anesthesia, using the same method. These patients are randomly divided into two groups of 36 patients. In the first group, patients receive fluid therapy with normal saline (10 cc/kg) and in the second group, patients receive one-fifth to four-fifths serum (10 cc/kg). The plasma glucose level will be measured at baseline, every half hour during the operation, the end of the operation, immediately after entering the neonatal ward, and 2 hours after entering the ward. Sodium serum will be measured and recorded before entering the operating room and immediately after entering the neonatal intensive care unit and 2 hours after entering the ward.

Participants/Inclusion and exclusion criteria

Inclusion criteria include babies 1 day to 30 days old, candidates for surgery with the same general anesthesia protocol, American Society of Anesthesiologists Classification I and II. Exclusion criteria include disagreement of the patient's parents to participate in the study.

Intervention groups

All patients undergo general anesthesia in the same way and after intubation with the appropriate size and maintenance anesthesia with oxygen and Isoflurane anesthesia will be performed. Then, patients in the first intervention group will receive fluid therapy with normal

saline (10 cc/kg) and in the second intervention group will receive fluid therapy with one-fifth-four-fifth serum (10 cc/kg).

Main outcome variables

Plasma sodium; Plasma Glucose

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200411047035N1**

Registration date: **2020-09-10, 1399/06/20**

Registration timing: **registered_while_recruiting**

Last update: **2020-09-10, 1399/06/20**

Update count: **0**

Registration date

2020-09-10, 1399/06/20

Registrant information

Name

Mina Azari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3665 1484

Email address

mina.azari10@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-31, 1399/06/10

Expected recruitment end date

2020-09-22, 1399/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of using two methods of fluid therapy with normal saline and one-fifth-four-fifth serum on plasma sodium and plasma glucose levels during and after neonatal surgery

Public title

Comparison of the effect of fluid therapy on plasma sodium and plasma glucose levels during and after neonatal surgery

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Babies 1 to 30 days old Candidate for surgery with the same general anesthesia protocol American Society of Anesthesiologists Classification I and II

Exclusion criteria:

Patient parents' disagreement to participate in the study

Age

From **1 day** old to **30 days** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be divided into two groups of 36 using block randomization method of block size 4. So that four patients are randomly selected in the first block, then two of them will be simple randomly assigned to the control and the other two ones assigned to the intervention group. Again, another four patients will be randomly selected in the second block and two of them will be simple randomly assigned to the control and the other two ones assigned to the intervention group. This selection of blocks and assignment will be continued for 18 times to make the control or intervention groups of 36 ones.

Blinding (investigator's opinion)

Triple blinded

Blinding description

In this study, normal saline and one-fifth-four-fifth serum are prepared by the pharmacist and placed in coded packages and delivered daily to an anesthesiologist. They also prescribe them without knowing the type of any of the drugs. Also, the person recording the clinical

and basic information of the patients as well as the statistical analyst will not be aware of the type of intervention.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jerib street

City

Esfahan

Province

Isfahan

Postal code

8174673461

Approval date

2020-03-05, 1398/12/15

Ethics committee reference number

IR.MUI.MED.REC.1398.635

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

Pediatric surgery

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Plasma sodiun levels

Timepoint

Sodium serum before entering the operating room and immediately after entering the neonatal intensive care unit and 2 hours after entering the intensive care unit

Method of measurement

Blood test

2**Description**

Plasma glucose level

Timepoint

Blood sugar levels during baseline, every half hour during and after surgery, and immediately after entering the neonatal intensive care unit and 2 hours after entering the ward.

Method of measurement

Glucometer device

Secondary outcomes

empty

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

All patients undergo general anesthesia in the same way and after intubation with the appropriate size and maintenance anesthesia with oxygen and Isoflurane anesthesia will be performed. Then, patients in the first intervention group will receive fluid therapy with normal saline (10 cc/kg).

Category

Treatment - Other

2**Description**

All patients undergo general anesthesia in the same way and after intubation with the appropriate size and maintenance anesthesia with oxygen and Isoflurane anesthesia will be performed. Then, patients in the second intervention group will receive fluid therapy with one-fifth-four-fifth serum (10 cc/kg)

Category

Treatment - Other

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

Emam hossein Children's Hospital

Full name of responsible person

Amir Shafa

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

Esfahan University of Medical Sciences

Full name of responsible person

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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

Esfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Amir Shafa

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available