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
Isfehan
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

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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