

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

Comparative study of two fluid therapy methods with either normal saline or DW5% NaCl 0.45% effect on blood glucose and plasma electrolyte levels during and after neonatal surgery

Protocol summary

Study aim

Assessing the effect of using either two methods of serum therapy with normal saline or dextrose half saline on vital signs, blood glucose level, sodium and bicarbonate serum levels and mean acidity and base excess of serum during and after neonatal surgery

Design

Clinical trial with two parallel groups, double blinded, block randomized, 78 cases

Settings and conduct

This study will be performed in Isfahan Imam Hossein hospital. The study is double blinded and the patients and statistical data analyzer are blinded.

Participants/Inclusion and exclusion criteria

Neonates aged 1 to 30 days candidate for surgery under general anesthesia with ASA one or two whose parents' have consented to participate in the study

Intervention groups

Intervention group A consists of neonates who will be receiving normal saline during surgery and intervention group B consists of neonates who will be receiving dextrose half saline during surgery.

Main outcome variables

Vital signs, Blood glucose level, Sodium and bicarbonate serum levels and mean acidity and base excess of serum

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200229046645N1**

Registration date: **2020-04-14, 1399/01/26**

Registration timing: **registered_while_recruiting**

Last update: **2020-04-14, 1399/01/26**

Update count: **0**

Registration date

2020-04-14, 1399/01/26

Registrant information

Name

Negin khavarian moghadam

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 87 3362 2634

Email address

negin.khavarian@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-19, 1398/12/29

Expected recruitment end date

2020-06-18, 1399/03/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of two fluid therapy methods with either normal saline or DW5% NaCl 0.45% effect on blood glucose and plasma electrolyte levels during and after neonatal surgery

Public title

Assessing the effect of fluid therapy with either normal saline or dextrose half saline on blood glucose and plasma electrolyte levels in neonatal surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Candidate for surgery under general anesthesia ASA=1,2

Parental consent of the patients to participate in the study

Exclusion criteria:

Presence of any underlying disease in the neonate

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **78**

More than 1 sample in each individual

Number of samples in each individual: **9**

Average heart rate, Average respiratory rate, Average of mean arterial pressure, Average percent of arterial blood O2 saturation, Average Sodium serum level, Average Bicarbonate serum level, Serum glucose level, Average serum pH, Average serum BE

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization is performed in a way that all blocks have the same size of six participants. Each block has three participants in the intervention group A and three participants in the intervention group B (Randomization is used to choose participants in each intervention group).

Blinding (investigator's opinion)

Double blinded

Blinding description

Parents of patients and data analyzer are unaware of how the patients are grouped.

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

Milad dormitory, dormitory collection of Isfahan

University of Medical science, Hezar Jerib Ave

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2018-12-05, 1397/09/14

Ethics committee reference number

IR.MUI.MED.REC.1398.183

Health conditions studied

1

Description of health condition studied

Vital signs during neonatal surgery, Mean serum sodium and bicarbonate during neonatal surgery, Mean acidity and base excess during neonatal surgery, Blood glucose level during neonatal surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Vital signs

Timepoint

Beginning of the surgery, 15th minute of the surgery, 30th minute of the surgery

Method of measurement

Patient monitoring machine

2

Description

Sodium and bicarbonate serum levels

Timepoint

Beginning of the surgery, End of the surgery, 2 hours after the surgery

Method of measurement

Blood sample

3

Description

Serum acidity and base excess

Timepoint

End of the surgery

Method of measurement

Blood sample

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group A: Patients who receive 10 cc per kilogram body weight normal saline as serum therapy during the surgery

Category

Treatment - Other

2

Description

Intervention group B: Patients who receive 10 cc per kilogram body weight dextrose half saline as serum therapy during the surgery

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan Imam Hossein hospital

Full name of responsible person

Amir Shafa

Street address

Imam Hossein hospital, Emam khomeini Blvd

City

Isfahan

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Postal code

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Phone

+98 31 3386 6266

Email

shafa_amir@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

shaghayegh haghjooye javanmard

Street address

Vice-Chancellery for Research and Technology,
Isfahan University of Medical science, Hezar Jerib Blvd

City

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Phone

+98 31 3668 5149

Email

research@mui.ac.ir

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

Negin Khavarian moghadam

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Anesthesiology

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Milad dormitory, Medical university of Isfahan's
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Person responsible for scientific inquiries

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Esfahan University of Medical Sciences

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to
make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to
make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to
make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to
make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to
make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available