Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Sep 2026

Comparative study of two fluid therapy methods with 5% glucose serum and 5% glucose in lactate ringer on serum glucose, sodium and potassium levels of neonates during and after surgery

Protocol summary

Study aim
Determination and comparison of two methods of fluid therapy with 5% glucose serum and 5% glucose in Ringer lactate on neonatal serum glucose, sodium and potassium levels during and after surgery

Design
In this double-blind randomized clinical trial study with parallel groups, 100 patients were randomly divided into two groups receiving 5% glucose serum and 5% glucose serum in ringer lactated by random allocation software.

Settings and conduct
This double-blind clinical trial study will be performed during 2021-2022 in Al-Zahra Hospital in Isfahan. Fluids are injected into the patient under the supervision of an anesthesiologist, but data collection will be performed by an experienced operating room staff member who is unaware of the infant's fluid therapy.

Participants/Inclusion and exclusion criteria
In this study, infants less than two months old who need surgery and do not have metabolic disorders are included in the study.

Intervention groups
100 baby infants for surgery are distributed in two groups of 50. In the first group, fluid therapy is performed using 5% dextrose serum and in the second group with 5% dextrose serum in ringer lactate.

Main outcome variables
Serum levels of blood glucose, sodium and potassium

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130311012782N57**
Registration date: **2021-11-29, 1400/09/08**
Registration timing: **prospective**
Last update: **2021-11-29, 1400/09/08**
Update count: **0**

Registration date
2021-11-29, 1400/09/08

Registrant information

Name
Ali Mehrabi kushki

Name of organization / entity
Isfahan University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 31 3629 1510

Email address
mehrabi@mui.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-12-21, 1400/09/30

Expected recruitment end date
2022-03-19, 1400/12/28

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparative study of two fluid therapy methods with 5% glucose serum and 5% glucose in lactate ringer on serum glucose, sodium and potassium levels of neonates during and after surgery

Public title
Comparison of fluid therapy with 5% glucose serum and

5% glucose in lactated ringer on serum glucose, sodium and potassium levels of infants during and after surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Infant candidate for surgery Age less than 2 months Parents' consent to participate in the study

Exclusion criteria:

Infant with metabolic disorders

Age

To **2 months** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization of patients is done using Random Allocation Software. In this software, the total sample size and number of groups are entered into the software. The software output is a list that randomly distributes the entire sample size between the two groups. Patients are divided into two groups according to the time of referral and according to the mentioned list to complete the sample size.

Blinding (investigator's opinion)

Double blinded

Blinding description

The method of blinding is as follows: Fluids are injected into the patient under the supervision of an anesthesiologist, but data collection will be done by one of the experienced operating room personnel who is unaware of the type of fluid therapy for the infant. Also, the data analyzer is unaware of the type of fluid received.

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

Sofeh street

City

Isfahan

Province

Isfehan

Postal code

8434193474

Approval date

2020-12-27, 1399/10/07

Ethics committee reference number

IR.MUI.MED.REC.1399.861

Health conditions studied

1

Description of health condition studied

Hyper glycemia

ICD-10 code

R73.9

ICD-10 code description

Hyperglycemia, unspecified

Primary outcomes

1

Description

Serum level of blood Glucose

Timepoint

before, during and after surgery

Method of measurement

Glucometer

2

Description

Serum level of Sodium

Timepoint

Before. during and after surgery

Method of measurement

With laboratory testing

3

Description

Serum level of potassium

Timepoint

Before, during and after surgery

Method of measurement

With laboratory testing

Secondary outcomes

1

Description

Blood pressure

Timepoint

Before surgery, during surgery, during recovery and 24 hours after surgery

Method of measurement
Pulse oximetry

2

Description
Heart rate
Timepoint
Before surgery, during surgery, during recovery and 24 hours after surgery
Method of measurement
Pulse oximetry

3

Description
Percentage of blood oxygen saturation
Timepoint
Before surgery, during surgery, during recovery and 24 hours after surgery
Method of measurement
Pulse oximetry

Intervention groups

1

Description
Intervention group1: Fluid therapy using 5% serum dextrose
Category
Prevention

2

Description
Intervention group 2: Liquid therapy with 5% dextro serum in ringer lactate
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra hospital
Full name of responsible person
Mohamad Farhoudi
Street address
Sofeh street
City
Isfahan
Province
Isfehan
Postal code
8434193474
Phone
+98 31 3669 2174
Email
mohamad.farhoudi@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Mansour Siavash
Street address
Herar Herib street
City
Isfahan
Province
Isfehan
Postal code
8434193474
Phone
+98 31 3792 3060
Email
m_siavash@med.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
Mohamad Farhoudi
Position
Resident
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Sofeh street
City
Isfahan
Province
Isfehan
Postal code
8434193474
Phone

+98 31 3668 2174

Email

mohamad.farhoudi@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Parvi Sajedi

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Sofeh street

City

Isfahan

Province

Isfehan

Postal code

8434193474

Phone

+98 31 3669 2174

Email

sahedi@med.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Ali Mehrabi

Position

Statistical Consultant

Latest degree

Master

Other areas of specialty/work

Epidemiology

Street address

Hezar Jerib street

City

Isfahan

Province

Isfehan

Postal code

8434193474

Phone

+98 31 3669 2174

Email

al.mehrabi@gmail.com

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

The plan belongs to a government organization and it is not possible to share it.

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