Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effect of intravenous Aminophylline injection on preventing renal dysfunction in the first living hours in neonates with asphyxia: A randomized clinical trial study

Protocol summary

Study aim
effects of Aminophylline on renal function of neonates with moderate and severe perinatal asphyxia

Design
In this randomized clinical trial conducted from June 2016 until May 2017, for 12 months, 50 neonates that These were born with moderate to severe asphyxia during birth were enrolled. They were divided randomly by using random blocks into two groups of 25. The case group were administered one dose of 5mg/kg slow intravenous aminophylline injection during 5 minutes. The control group were administered 2 milliliters of intravenous 10% solution of dextrose saline as placebo with the same conditions as the case group.

Settings and conduct
Double-blinded randomized clinical trial in NICU of selected hospital of Iran university of medical science.

Participants/Inclusion and exclusion criteria
Inclusion criteria: The neonates with moderate and severe perinatal asphyxia Exclusion criteria: Congenital Anomalies; Prematurity (Gestational age≥37 week)

Intervention groups
The case group were administered one dose of 5mg/kg slow intravenous aminophylline injection during 5 minutes. The control group were administered 2 milliliters of intravenous 10% solution of dextrose saline as placebo with the same conditions as the case group

Main outcome variables
The neonates' fluid intake, Urine volume in the first three days, serum electrolytes including Sodium, Potassium, Calcium, serum Creatinine and GFR were monitored. The two groups were also monitored and compared for complications of prenatal asphyxia.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181201041815N1**
Registration date: **2019-01-15, 1397/10/25**
Registration timing: **retrospective**

Last update: **2019-01-15, 1397/10/25**
Update count: **0**

Registration date
2019-01-15, 1397/10/25

Registrant information

Name
Nasrin Khalessi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 2222 2041

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khalesi.n@iums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2016-05-21, 1395/03/01

Expected recruitment end date
2017-06-22, 1396/04/01

Actual recruitment start date
2016-05-21, 1395/03/01

Actual recruitment end date
2017-06-22, 1396/04/01

Trial completion date
2017-06-22, 1396/04/01

Scientific title
Effect of intravenous Aminophylline injection on

preventing renal dysfunction in the first living hours in neonates with asphyxia: A randomized clinical trial study

Public title
Effect of intravenous Aminophylline injection on preventing renal dysfunction
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Neonate with Moderate and Severe Asphyxia
Exclusion criteria:
Congenital Anomalies Prematurity(Gestational age≥37 week)
Age
To **30 days** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **50**
Actual sample size reached: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
A randomized blocking method of four blocking was used using R statistical software.
Blinding (investigator's opinion)
Double blinded
Blinding description
The participants (neonate), researcher, therapist and the evaluator were informed of the allocation in the intervention group.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
Street address
School Of Medicine,Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Approval date
2015-10-31, 1394/08/09
Ethics committee reference number
IR.IUMS.REC 1395.8821215173

Health conditions studied

1

Description of health condition studied
Recovery of moderate to severe asphyxia in newborns
ICD-10 code
R09.0
ICD-10 code description
Asphyxia and hypoxemia

Primary outcomes

1

Description
The neonates’ fluid intake
Timepoint
Before and after the intervention 24 hours after intervention and during the 4th and 7th day of life
Method of measurement
Using Schwartz's formula, in two studied groups.

2

Description
Urine volume in the first three days,
Timepoint
Before and after the intervention 24 hours after intervention and during the 4th and 7th day of life
Method of measurement
Using Schwartz's formula, in two studied groups.

3

Description
Serum electrolytes including Sodium, Potassium, Calcium, serum Creatinine
Timepoint
Before and after the intervention 24 hours after intervention and during the 4th and 7th day of life
Method of measurement
Using Schwartz's formula, in two studied groups.

4

Description
GFR
Timepoint
Before and after the intervention 24 hours after intervention and during the 4th and 7th day of life

Method of measurement
Using Schwartz's formula, in two studied groups.

Secondary outcomes

1

Description
Lung disease
Timepoint
During the 4th and 7th day of life
Method of measurement
Chest X ray

2

Description
Intra Ventricular Hemorrhages seizure
Timepoint
During the 4th and 7th day of life
Method of measurement
Brain sonography and nursing documentation related to seizure.

3

Description
Death
Timepoint
During the 4th and 7th day of life
Method of measurement
Shift documentation

Intervention groups

1

Description
Intervention group: were administered one dose of 5 mg/kg slow intravenous Aminophylline injection during 5 minutes.
Category
Treatment - Drugs

2

Description
Control group: The control group was administered 2 milliliters of intravenous 10% solution of dextrose saline as placebo with the same conditions as the case group
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Aliasghar hospital
Full name of responsible person
Nasrin Khalessi
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Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran
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Recruitment center
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shahid Akbar-Abadi
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
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+98 21 86701
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nasrinkhalessi@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Nasrin Khalessi
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Data and documentation are arranged in separate files and after publishing the results ready to distribution.
When the data will become available and for how long
7-10 days
To whom data/document is available
Every body that will be re analyzed or meta-analyzed.
Under which criteria data/document could be used
In order to perform more robust statistical tests that may occur in the future. Or the person who intends to do meta-analysis.

From where data/document is obtainable

Aliasghar hospital- Neonatal Intensive Care Unit-Dr Nasrin khalessi-

What processes are involved for a request to access data/document

The demandant person will request Dr. Khalesi by email and the files will be sent to them.

Comments