

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 $\geq$ 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)

Phone

+98 21 2222 2041

Email address

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	
<u>1</u>	
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	۱۴۳۹۶۱۴۵۳۵
Approval date	2015-10-31, 1394/08/09
Ethics committee reference number	IR.IUMS.REC 1395.8821215173
Health conditions studied	
<u>1</u>	
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	
<u>1</u>	
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.
<u>2</u>	
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.
<u>3</u>	
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.
<u>4</u>	
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

Street address

Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran

City

Tehran

Province

Tehran

Postal code

۱۹۱۹۸۱۶۷۶۶

Phone

+98 21 2222 2041

Email

nasrinkhalessi@yahoo.com

2

Recruitment center

Name of recruitment center

shahid Akbar-Abadi

Full name of responsible person

Nasrin Khalessi

Street address

Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran

City

Tehran

Province

Tehran

Postal code

۱۹۱۹۸۱۶۷۶۶

Phone

+98 21 2222 2041

Email

nasrinkhalessi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Nasrin Khalessi

Street address

Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran

City

Tehran

Province

Tehran

Postal code

۱۴۳۹۶۱۴۵۳۵

Phone

+98 21 86701

Email

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

Street addressIran University of Medical Sciences, Shahid Hemmat
Highway, Tehran**City**

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Phone

+98 21 86701

Email

nasrinkhalessi@yahoo.com

Person responsible for scientific 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

Street addressIran University of Medical Sciences, Shahid Hemmat
Highway, Tehran**City**

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Phone

+98 21 86701

Email

nasrinkhalessi@yahoo.com

Person responsible for updating data**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

Street addressIran University of Medical Sciences, Shahid Hemmat
Highway, Tehran**City**

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Phone

+98 21 86701

Email

nasrinkhalessi@yahoo.com

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/documentData 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 usedIn 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. Khalessi by email
and the files will be sent to them.

Comments