

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Comparison of the effect of two drugs Allopurinol and Aminophylline in the treatment of neonates with asphyxia

Protocol summary

Study aim

Comparison of The effect of Aminophylline and Allopurinol in the treatment of neonates with asphyxia

Design

In the first hour, the first group received 5 mg / kg intravenous Aminophylline as a STAT and two hours after neonatal admission to the Neonatal Intensive Care Unit (NICU) with a maintenance dose of 1 mg / kg Aminophylline at a rate of 60-60 cc / kg / day every 12 They find the clock for a week. The second group received 40 mg / kg Allopurinol daily for 7 days two hours after birth and hospitalized in the ward (NICU). The control group received 5% dextrose volume.

Settings and conduct

All neonates with asphyxia admitted to the Neonatal Intensive Care Unit (NICU) of Shoushtar Hospital in 2019

Participants/Inclusion and exclusion criteria

Inclusion criteria (Apgar score less than 5 and cord artery pH less than 7.2) and Exclusion criteria based on AAP guideline (premature infants with congenital and chromosomal abnormalities and abnormalities of mother and gestational diabetes mellitus)

Intervention groups

They were randomly divided into group 30 (Aminophylline), group 30 (Allopurinol) and group 30 (control).

Main outcome variables

Kidney function (BUN and Cr) Brain function (DRT index and reflexes)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20121229011923N7**

Registration date: **2019-12-23, 1398/10/02**

Registration timing: **prospective**

Last update: **2019-12-23, 1398/10/02**

Update count: **0**

Registration date

2019-12-23, 1398/10/02

Registrant information

Name

Akram Hematipour

Name of organization / entity

Ahvaz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 1373 8302

Email address

hematipour.a@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-20, 1398/12/01

Expected recruitment end date

2022-02-20, 1400/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of two drugs Allopurinol and Aminophylline in the treatment of neonates with asphyxia

Public title

Comparison of the effect of two drugs Allopurinol and Aminophylline in the treatment of neonates with asphyxia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

5 minute apgar less than 5 The pH of the cord artery is less than

Exclusion criteria:

Parental dissatisfaction Premature infants with congenital and chromosomal abnormalities and renal and abdominal malformations Mother with gestational diabetes

Age

From **1 day** old to **1 day** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

It will be randomly selected and will consist of 4-person blocks using the block randomization method

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

کمیته اخلاق دانشکده علوم پزشکی شوشتر

Street address

Rajae West Ave., Faculty of Medical Sciences
Shoushtar

City

Shoushtar

Province

Khuzestan

Postal code

84534-64516

Approval date

2019-07-10, 1398/04/19

Ethics committee reference number

IR.SHOUSHTAR.REC.1398.010

Health conditions studied

1

Description of health condition studied

Asphyxia

ICD-10 code

R09.01

ICD-10 code description

Asphyxia

Primary outcomes

1

Description

Improve kidney function

Timepoint

To evaluate the performance of all BUN, Cr and electrolyte measurements (Na and k) one day in between for one week

Method of measurement

Blood test

2

Description

Improve brain function

Timepoint

Daily

Method of measurement

The nervous system is also monitored daily by Moro, sucking, Grasping reflexes and the DTR index (deep tendon reflex). And if they are normal, we move one shot at a time, and we have the same direction with the muscle that we hit. Depending on the reflex we can score 4 (score 0): Under no circumstances can reflex be achieved, (+1 score): We can get reflex when the patient is distracted and reflex is reduced (+2 score) : The reflex is normal, (+3 score) when we have expansion at the point of insertion (reflex can also be achieved at other locations), (+4 score): when clonus This means that when a blow is made, the reflex is repeated several times, and the movement is repeated several times, with a score of 0 or 4 and 3 meaning a brain injury.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the first hour, the first intervention group received 5mg / kg intravenous aminophylline as STAT and two hours after neonatal admission to the neonatal intensive care unit (NICU) 1mg / kg infusion with a maintenance dose of 65 -60cc / kg / day are found every 12 hours for a week.

Category

Treatment - Drugs

2

Description

Intervention group: Allopurinol 40 mg / kg daily for 7 days two hours after birth and in hospital (NICU) intravenously

Category

Treatment - Drugs

3

Description

Control group: Treatment will continue without any intervention

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shoushtar Elahadi Hospital

Full name of responsible person

Akram Hemmatipour

Street address

West Rajaie Street

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64516- 84534

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Email

hematipour.a64@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Faculty of Medical Sciences Shoushtar

Full name of responsible person

Mojtaba Kalantar

Street address

Rajae West Ave., Faculty of Medical Sciences
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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

Faculty of Medical Sciences Shoushtar

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

Faculty of Medical Sciences Shoushtar

Full name of responsible person

Akram Hemmatipour

Position

University professor

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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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

no

When the data will become available and for how long

no

To whom data/document is available

no

Under which criteria data/document could be used

no

From where data/document is obtainable

no

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

no

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Faculty of Medical Sciences Shoushtar

Full name of responsible person

Akram Hemmatipour

Position

University professor

Latest degree

Master

Other areas of specialty/work

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