

# 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

##### City

Shoushtar

##### Province

Khouzestan

##### Postal code

64516- 84534

##### Phone

+98 61 3622 2221

##### 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  
Shoushtar

##### City

Shoushtar

##### Province

Khouzestan

##### Postal code

84534-64516

##### Phone

+98 61 3622 2221

##### Email

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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

### Contact

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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**

Nursery

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