

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jun 2026

### Adverse kidney effects of standard -daily dosing versus once daily dosing of amikacin among preterm neonates

#### Protocol summary

##### Summary

The aim of this study is to compare the renal damage caused by standard and once daily dose of Amikacin in premature infants with suspected sepsis. According to formula, the sample volume will be 40 infants. This study will be carried out in "Shahid Akbar Abadi" Hospital. Inclusion criteria: Preterm infants with normal intrauterine growth and sepsis suspicion at birth. Exclusion criteria: Neonate who received incomplete treatment; Parents dissatisfaction for continuation of treatment; asphyxia; renal anomalies in ultrasound after birth. Preterm neonates with sepsis diagnosis will be divided to two groups (A and B) randomly. One group of neonates will receive standard dose of Amikacin and the other one, single daily dose. All of them will also receive 100 mg / kg / d Ampicillin each 8 or 12- hour. Before initializing the treatment, CBC, diff, blood culture, BUN, creatinine and urinary N-GAL will be checked. To rule out renal anomalies in infants during the first week after birth, ultrasound of the kidneys and urinary tract will be done. CBC, diff, BUN and creatinine will be rechecked on the third and fifth days of the treatment. In both groups, maximum and minimum of Amikacin serum level will be checked. The maximum Amikacin serum level will be reached 30 minutes after injection. With this sample the level of creatinine in the blood will also be checked. To determine the minimum level of Amikacin serum, sampling is done 30 minutes before the first injection of Amikacin on the fifth day. With this sample serum creatinine level is also measured. Urinary NGAL levels will be measured on the seventh day. Sampling will continue to the seventh day of treatment and until the number of children who have urinary N-GAL levels in each group (A and B) reaches 20. To study the adverse effects of Amikacin on kidneys, serum creatinine level and urinary N-GAL will be used.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015103124804N1**

Registration date: **2016-02-05, 1394/11/16**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-02-05, 1394/11/16

##### Registrant information

##### Name

Arash Bordbar

##### Name of organization / entity

Iran university of medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2296 9030

##### Email address

bordbar.a@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Iran University of Medical Sciences

##### Expected recruitment start date

2015-11-22, 1394/09/01

##### Expected recruitment end date

2016-02-20, 1394/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Adverse kidney effects of standard -daily dosing versus once daily dosing of amikacin among preterm neonates

## Public title

Adverse effects of amikacin on preterm infants kidneys

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria:Appropriate for gestational age preterm infants with early onset sepsis diagnosis Exclusion criteria:neonates with incomplete treatment ; whom their parents do not accept to be included in this trial ; asphyxia; kidney anomalies in ultrasonography

## Age

To **7 days** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **40**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Triple blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Iran University of Medical Sciences

##### Street address

Tehran, Iran

##### City

Tehran

##### Postal code

#### Approval date

2015-09-01, 1394/06/10

#### Ethics committee reference number

IR.IUMS.REC.1394.9111165005

## Health conditions studied

### 1

#### Description of health condition studied

Bacterial sepsis of newborn

#### ICD-10 code

P36

#### ICD-10 code description

Bacterial sepsis of newborn

## Primary outcomes

### 1

#### Description

Urinary NGAL rising

#### Timepoint

at admission before initialling amikacin and at 7th day after completing treatment

#### Method of measurement

Using Urinary NGAL kit

## Secondary outcomes

### 1

#### Description

serum cr & BUN rising

#### Timepoint

at admission and 3th, 5th and 7th day

#### Method of measurement

by blood sampling

## Intervention groups

### 1

#### Description

Amikacin administration as once daily dose intravenously for 7 days

#### Category

Treatment - Drugs

### 2

#### Description

Amikacin administration as standard daily dose intravenously for 7 days

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid Akbarabadi Hospital

##### Full name of responsible person

Dr Arash Bordbar

##### Street address

Shahid Akbarabadi Hospital, Mowlavi st, Tehran, Iran

##### City

Tehran

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Dr Seyyed Ali Javad Mousavi

**Street address**

Iran University of Medical Sciences, Tehran, Iran

**City**

Tehran

**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**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Arash Bordbar

**Position**

Neonatologist/ Professor Assistant

**Other areas of specialty/work**

**Street address**

Shahid Akbarabadi Hospital, Mowlavi st, Tehran,Iran

**City**

Tehran

**Postal code**

1168743514

**Phone**

+98 21 2296 9030

**Fax**

+98 21 5560 8012

**Email**

bordbar.a@iums.ac.ir  
drarashbordbar@gmail.com  
ordbar@yahoo.com

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Iran university of medical sciences

**Full name of responsible person**

Arash Bordbar

**Position**

Neonatologist/ Professor Assistant

**Other areas of specialty/work**

**Street address**

Shahid Akbarabadi Hospital, Mowlavi st, Tehran, Iran

**City**

Tehran

**Postal code**

1168743514

**Phone**

+98 21 2296 9030

**Fax**

+98 21 5560 8012

**Email**

bordbar.a@iums.ac.ir  
drarashbordbar@gmail.com

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Iran university of medical sciences

**Full name of responsible person**

Arash Bordbar

**Position**

Neonatologist/ Professor Assistant

**Other areas of specialty/work**

**Street address**

Shahid Akbarabadi Hospital, Mowlavi st, Tehran, Iran

**City**

Tehran

**Postal code**

1168743514

**Phone**

+98 21 2296 9030

**Fax**

+98 21 5560 8012

**Email**

bordbar.a@iums.ac.ir  
drarashbordbar@gmail.com  
ordbar@yahoo.com

**Web page address**

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*