

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The survey of the effect of parenteral caffeine citrate for prevention of apnea in very preterm neonates in NICU part of Shahid-Motahary hospital for one year

#### Protocol summary

##### Summary

This study is conducted in preterm infants with a gestational age of 32 weeks and less and birth weight less than 1500 grams in the NICU department of Shahid-Motahary Hospital. Infants are randomly assigned into two groups: Infants of group A on the second day of birth (24-48 h) intravenous caffeine citrate with a dose of 20mg/kg and then the maintenance dose 24 hours after the first injection with a dose of 5mg/kg daily injected. Group B received no caffeine. Infants undergo cardiopulmonary monitoring and control heart rate and respiratory rate, as well as arterial oxygen saturation control. Apnoeic attacks reported by nurses on cyanotic attacks and loss of saturation will be documented (on special charts of the researcher). Given the effectiveness of the birth weight, patients divided into three groups (less than 1000 grams, 1,249,1250-1500) and the weight of the birth is divided into three groups, in order to compare the two groups in terms of the same confounding factors. Newborns in the control group will undergo standard treatment if they develop apnea. In addition, the two groups will not differ in their routine neonatal therapies, such as administration of total parenteral nutrition (TPN) and antibiotics.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017102637023N1**

Registration date: **2017-11-14, 1396/08/23**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-11-14, 1396/08/23

#### Registrant information

##### Name

Zahra Fakoor

##### Name of organization / entity

Urmia University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 44 3224 4830

##### Email address

drfakoor@umsu.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Investigator

#### Expected recruitment start date

2017-01-20, 1395/11/01

#### Expected recruitment end date

2017-09-20, 1396/06/29

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

The survey of the effect of parenteral caffeine citrate for prevention of apnea in very preterm neonates in NICU part of Shahid-Motahary hospital for one year

#### Public title

Effect of parenteral caffeine citrate for prevention of apnea in very preterm neonates in NICU ward

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion criteria for entering were the premature

newborns weighing less than 1500 grams at least 24 hours of age and having self-contained breathing in the first 24 hours of life; and exclusion criteria were maternal major anomalies, the incidence of apnea in the first 24 hours of life and the need for mechanical ventilation in 24 The first hour of birth, cyanotic heart disease, small age for gestational age (SGA, IUGR), intrauterine growth retardation, as well as clinical evidence for sepsis during the first 7 days of birth and IVH grade 3 or 4 during the first week of life.

#### Age

From **1 day** old to **8 months** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **100**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Urmia University of Medical Sciences

##### Street address

Urmia Street - Head of Urmia University of Medical Sciences

##### City

Urmia

##### Postal code

#### Approval date

2016-12-09, 1395/09/19

#### Ethics committee reference number

IR.UMSU.REC.1395.360

## Health conditions studied

### 1

#### Description of health condition studied

Apnoea

#### ICD-10 code

P28.3

#### ICD-10 code description

Primary sleep apnoea of newborn

## Primary outcomes

### 1

#### Description

Apnoea

#### Timepoint

From beginning to end of intervention

#### Method of measurement

The number of cases of apnoea reported by the nurse

## Secondary outcomes

### 1

#### Description

Bradycardia

#### Timepoint

From beginning to end of intervention

#### Method of measurement

The number of cases of bradycardia reported by the nurse

### 2

#### Description

Cyanosis

#### Timepoint

From beginning to end of intervention

#### Method of measurement

The number of cases of cyanosis reported by the nurse

### 3

#### Description

Duration of oxygen demand

#### Timepoint

From beginning to end of intervention

#### Method of measurement

Duration of oxygen demand reported by the nurse

### 4

#### Description

Duration of NCPAP demand

#### Timepoint

From beginning to end of intervention

#### Method of measurement

Duration of NCPAP demand reported by the nurse

### 5

#### Description

Duration of mechanical ventilation demand

#### Timepoint

From beginning to end of intervention

#### Method of measurement

Duration of mechanical ventilation demand reported by

the nurse

## 6

### Description

hospitalization

### Timepoint

From beginning to end of intervention

### Method of measurement

Patients' Records

## Intervention groups

### 1

#### Description

Control received no caffeine.

#### Category

Placebo

### 2

#### Description

Infants of intervention group on the second day of birth (24-48 h) intravenous caffeine citrate with a dose of 20mg/kg and then the maintenance dose 24 hours after the first injection with a dose of 5mg/kg daily injected.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Urmia Shahid-Motaharii Hospital

##### Full name of responsible person

##### Street address

##### City

Urmia

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Urmia University of Medical Sciences

##### Full name of responsible person

Dr Iraj Mohebbi

##### Street address

Head of Urmia University of Medical Science, Urjans alley, Pezeshkian Street.

##### City

Urmia

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Urmia 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

Urmia University of Medical Sciences

##### Full name of responsible person

Dr Zahra Fakoor

##### Position

Associate professor of neonates

##### Other areas of specialty/work

##### Street address

Shahid-Motaharri Hospital

##### City

Urmia

##### Postal code

##### Phone

+98 44 3224 4830

##### Fax

##### Email

drfakoor@umsu.ac.ir

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Urmia University of Medical Sciences

##### Full name of responsible person

Dr Zahra Fakoor

##### Position

Associate professor of neonates

##### Other areas of specialty/work

##### Street address

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Dr Zahra Fakoor

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## 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*