

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Prophylactic caffeine for prevention of apnea in preterm neonate with weight less than 1200 gr.

Protocol summary

Summary

A few studies have been done about preventive drugs for apnea of preterm infants so we decided to investigate the prophylactic effects of caffeine on the incidence of apnea, bradycardia and cyanosis in higher risk neonate (preterm neonate with a weight below 1200 grams). In our study the prophylactic effect of caffeine on the apnea incidence will be investigated in two groups of caffeine given (group C) and control (group P). In the caffeine given group (C), after considering the inclusion and exclusion criteria, 20 mg/kg caffeine as loading dose was begun then each day, 5 mg/kg as maintenance dose was used until first 10 days of life. In control group, no caffeine was used in first 10 days of life.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013110610026N3**

Registration date: **2014-02-09, 1392/11/20**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-02-09, 1392/11/20

Registrant information

Name

Amir mohammad Armanian

Name of organization / entity

Isfahan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences, Isfahan, Iran

Expected recruitment start date

2013-09-01, 1392/06/10

Expected recruitment end date

2014-01-30, 1392/11/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Prophylactic caffeine for prevention of apnea in preterm neonate with weight less than 1200 gr.

Public title

Prophylactic caffeine for prevention of apnea in preterm neonate with weight less than 1200 gr.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria are infants born premature and at birth weight equal and lower than 1200 grams and spontaneous breathing at age 24 hours. Infants who have major congenital anomalies; asphyxia; occurrence of apnea and need to mechanical ventilation in first 24 hours of birth; congenital cyanotic heart disease and sepsis in the first seven days of birth will excluded.

Age

To **1 year** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 50

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezarjerib
Av, Isfahan, Iran

City

Isfahan

Postal code

Approval date

2012-09-22, 1391/07/01

Ethics committee reference number

292152

Health conditions studied

1

Description of health condition studied

Apnea

ICD-10 code

P28.3

ICD-10 code description

Primary sleep apnea of newborn p28.3

Primary outcomes

1

Description

Bradycardia

Timepoint

10 days

Method of measurement

nursing documentation and monitor download

2

Description

Neonatal apnea

Timepoint

10 days

Method of measurement

Daily recorded sheets

3

Description

Cyanosis

Timepoint

10 days

Method of measurement

nursing documentation and monitor download

Secondary outcomes

1

Description

Side effects

Timepoint

10 days

Method of measurement

daily recorded sheets

2

Description

Mechanical ventilation

Timepoint

10 days

Method of measurement

daily recorded sheets

3

Description

Oxygen dependency time

Timepoint

During Oxygen dependency time

Method of measurement

daily recorded sheets

4

Description

continuous positive air way pressure (CPAP)

Timepoint

10 days

Method of measurement

daily recorded sheets

5

Description

Hospital stay

Timepoint

10 days

Method of measurement

daily recorded sheets

6

Description

Death

Timepoint

During hospital stay

Method of measurement

daily recorded sheets

Intervention groups

1

Description

In the caffeine given group (C), after considering the inclusion and exclusion criteria for the premature neonate with a weight equal and lower than 1200 gr. who is breathing spontaneously at age 24 hours, 20 mg/kg caffeine as loading dose will be begun (parenteral) then each day, 5 mg/kg as maintenance dose will be used until first 10 days of life.

Category

Treatment - Drugs

2

Description

In control group (P), after considering the inclusion and exclusion criteria for the premature neonate with a weight equal and lower than 1200 gr. who is breathing spontaneously at age 24 hours, no caffeine was used in first 10 days of life.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Neonatal intensive care unit (NICU) at Alzahra and Shahid Beheshti hospitals in Isfahan-Iran

Full name of responsible person

Dr.Amir Mohammad Armanian

Street address

Number 133, shahid ansari Alley, Saeb Street, Isfahan, Iran

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Dr. Ebrahim Esfandiari

Street address

Faculty of Medicine, Isfahan University of Medical Sciences, Hezar-Jerib St., Isfahan, Iran

City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Isfahan 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

Department of Pediatrics, Isfahan University of Medical Sciences, Isfahan, Iran

Full name of responsible person

Dr. Eiman Faghihian

Position

Resident of pediatrics

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Child Growth and Development Research Center, Isfahan University of Medical Sciences

Full name of responsible person

Amir Mohammad Armanian

Position

Neonatologist

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

Dr. Amir Mohammad Armanian

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Other areas of specialty/work

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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