Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effect of prophylactic Caffeine on the need for oxygen duration and respiratory support in preterm neonates with weight 1250-2000 gr with RDS requiring nasal CPAP

Protocol summary

Study aim

In our study the effect of caffeine on the need for oxygen duration and respiratory support in preterm neonate with weight 1250-2000 gr with RDS requiring nasal CPAP will be investigated in two groups of caffeine given (group C) and control (group P).

Design

This study is a single blinded interventional randomized controlled clinical trial phase3 with 2 parallel groups (45 patients in each group). A Sequentially numbered computerized randomization with sealed opaque envelopes will be used for randomization.

Settings and conduct

The study sample consisted of infants with spontaneous breathing and clinical signs and symptoms of RDS, and requiring nasal CPAP admitted to the Neonatal intensive care unit (NICU) at Alzahra and Shahid Beheshti hospitals in Isfahan- Iran. After considering the inclusion and exclusion criteria, the neonate, randomized to caffeine (group C) and control (group P). In the caffeine group (C), caffeine will start on the 1st day of life and will continue until discontinuation of CPAP and oxygen administration. In control group, no caffeine or placebo will use.

Participants/Inclusion and exclusion criteria

The inclusion criteria included newborns with a gestational age less than 36 weeks and 6 days; newborns with spontaneous breathing and clinical signs and symptoms of RDS and requiring nasal CPAP. The exclusion criteria are 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

Intervention groups

In the caffeine given group (C), 20 mg/kg caffeine as loading dose was begun then each day, 10 mg/kg as maintenance dose was used until discontinuation of CPAP and oxygen administration. In control group, no caffeine was used.

Main outcome variables

The duration of respiratory support with oxygen and CPAP

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170627034782N2**
Registration date: **2019-12-12, 1398/09/21**
Registration timing: **registered_while_recruiting**

Last update: **2019-12-12, 1398/09/21**
Update count: **0**

Registration date

2019-12-12, 1398/09/21

Registrant information

Name
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Name of organization / entity
Isfahan University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-11, 1398/08/20

Expected recruitment end date

2020-06-09, 1399/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of prophylactic Caffeine on the need for oxygen duration and respiratory support in preterm neonates with weight 1250-2000 gr with RDS requiring nasal CPAP

Public title

Effect of prophylactic Caffeine on duration of respiratory support in preterm neonates with RDS

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Newborns with a gestational age less than 36 weeks and 6 days Birth weight between 1250 and 2000 gram Spontaneous breathing and clinical signs and symptoms of RDS Requiring nasal CPAP

Exclusion criteria:

Major congenital anomalies Asphyxia Occurrence of apnea and need to mechanical ventilation in first 24 hours of birth Congenital cyanotic heart disease Sepsis in the first seven days of birth

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Ṣequentially numbered computerized randomization, sealed opaque envelopes

Blinding (investigator's opinion)

Single blinded

Blinding description

Only neonates who participate in the study do not know how to prescribe medicine

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran National committee for Ethics in Biomedical Research

Street address

Research deputy, Isfahan University of Medical Sciences, Hezarjerib Blvd

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Isfehan

Postal code

8184757851

Approval date

2019-10-09, 1398/07/17

Ethics committee reference number

IR.MUI.MED.REC.1398.355

Health conditions studied

1

Description of health condition studied

neonatal respiratory distress syndrome

ICD-10 code

P22.0

ICD-10 code description

Respiratory distress syndrome of newborn

Primary outcomes

1

Description

Duration of respiratory support with nasal CPAP

Timepoint

Hourly, since birth till discontinuation of nasal CPAP

Method of measurement

Report in special charts of neonatal intensive care unit every hour

Secondary outcomes

1

Description

Apnea of prematurity

Timepoint

Hourly, since birth till discharge

Method of measurement

Cardio-respiratory monitoring in daily recorded sheet

2

Description

Duration of oxygen need

Timepoint

Hourly, since birth till discharge

Method of measurement

Daily recorded sheet

3

Description

Duration of hospitalization

Timepoint

Daily

Method of measurement

Daily recorded sheet

4

Description

Patent ductus arteriosus

Timepoint

Daily

Method of measurement

Cardiac exam and echocardiography if necessary

5

Description

Chronic lung disease

Timepoint

Daily

Method of measurement

Physical exam and chest-xray

6

Description

Pneumothorax

Timepoint

Hourly, since birth till discharge

Method of measurement

Physical exam and chest-xray

7

Description

Nosocomial infection

Timepoint

Daily

Method of measurement

Blood culture

8

Description

Seizure

Timepoint

Daily

Method of measurement

Daily recorded sheet

9

Description

Time to full enteral feed

Timepoint

Daily

Method of measurement

Daily recorded sheet

10

Description

Intraventricular hemorrhage

Timepoint

Third day of life

Method of measurement

Brain sonography

11

Description

Necrotizing enterocolitis

Timepoint

Daily

Method of measurement

Physical exam and abdominal-xray

Intervention groups

1

Description

Intervention group: In the caffeine given group (C), the premature neonate with a weight between 1250-2000 germ and spontaneous breathing with clinical signs and symptoms of RDS and requiring nasal CPAP, 20 mg/kg caffeine as loading dose will be begun (parenteral) and then each day, 10 mg/kg as maintenance dose will be used until discontinuation of CPAP and oxygen administration .

Category

Treatment - Drugs

2

Description

Control group:In control group (P), the premature neonate with a weight between 1250-2000 germ and spontaneous breathing with clinical signs and symptoms of RDS and requiring nasal CPAP no caffeine or placebo was used.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-zahra hospital, Isfahan

Full name of responsible person

Ramin Iranpour

Street address

No.16, Sout Resalat St., Mardavij Ave.

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2

Recruitment center

Name of recruitment center
Beheshti Hospital, Isfahan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Bahram Nasr esfahani

Street address
Hezrjerib Ave,Isfahan University of Medical Sciences, Isfahan Medical faculty

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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
Esfahan University of Medical Sciences

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
Esfahan University of Medical Sciences

Full name of responsible person
Ramin Iranpour

Position
Associate professor of Pediatrics in Isfahan medical faculty

Latest degree
Subspecialist

Other areas of specialty/work
Pediatrics

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Position
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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable