Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation and comparison of efficacy and adverse drug reactions for single or two divided caffeine dosing and simulation of pharmacokinetic parameters to treat apnea of prematurity in preterm neonates

Protocol summary

Summary

Apnea of prematurity is a common disease due to physiological immaturity in breathing control system of preterm infants.Treatment options are limited and include supportive therapy, continuous positive airway pressure (CPAP) and methylxanthines. Patients who not respond to these interventions require intubation and mechanical ventilation. Methylxanthines such as caffeine administered to stimulate breathing and reduce needing for mechanical ventilation in preterm infants. Different doses of this drug have been used in the preterm infants. However, more studies are needed to determine the optimal dose of caffeine in infants. The relation of caffeine pharmacodynamics and pharmacokinetics in neonates is not well known and a little data available about the correlation of pharmacokinetics and clinical effects. The aim of this study was evaluation the caffeine effects and determining the pharmacokinetics parameters in the apnea treatment in the premature infants. Neonates who diagnosed with apnea and gestational age of <37 weeks, was administered the loading dose of 20 milligrams per kilogram of caffeine intravenously. The maintenance dose of caffeine was infused to infants of group1 and group2 as 5 mg per kilogram once daily or 2.5 mg per kilogram twice daily respectively. The infant's plasma samples were used to measure plasma concentrations of caffeine. The rate of extubation and CPAP failure and length of stay in NICU were compared between two groups of patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201510172342N4**
Registration date: **2017-01-05, 1395/10/16**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2017-01-05, 1395/10/16

Registrant information

Name
Mohammad Reza Rafati
Name of organization / entity
Mazandaran University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 15 1354 3083
Email address
mrrafati@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences

Expected recruitment start date

2015-05-06, 1394/02/16

Expected recruitment end date

2016-08-21, 1395/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation and comparison of efficacy and adverse drug reactions for single or two divided caffeine dosing and simulation of pharmacokinetic parameters to treat apnea of prematurity in preterm neonates

Public title

Evaluation and comparison of efficacy and adverse drug reactions for single or two divided caffeine dosing to treat apnea of prematurity in preterm neonates

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Neonates with gestational age of 37 weeks exclusion criteria: asphyxia, hypoglycemia, intracranial hemorrhage, major inherited anomaly

Age

From **1 day** old to **1 month** 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)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mazandaran University of Medical Science

Street address

Office Building ,Juibar Three Way, ,Emam Square,Sari

City

Sari

Postal code

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

IR.MAZUMS.REC.95.1759

Health conditions studied

1

Description of health condition studied

Apnea of prematurity

ICD-10 code

P07.3

ICD-10 code description

Other preterm infants

Primary outcomes

1

Description

Extubation failure

Timepoint

during treatment

Method of measurement

Clinical observations

2

Description

CPAP failure

Timepoint

during treatment

Method of measurement

clinical observations and levels of blood gases in ABG

Secondary outcomes

1

Description

adverse reactions

Timepoint

during the treatment

Method of measurement

Questionnaire

Intervention groups

1

Description

control group: dose of 5 mg/ kg once daily group 1

Category

Treatment - Drugs

2

Description

intervention group: dose of 2.5 mg/ kg twice daily in Group 2

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Neonatal Intensive Critically Unit of Bu-Ali Hospital

Full name of responsible person

Street address

City

Sari

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for Research, Mazandaran University of Medical Sciences
Full name of responsible person
Dr Ahamadali Enayati
Street address
Next to 13 Aban Pharmacy,Moalem square,Sari
City
Sari
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for Research, Mazandaran 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
Mazandaran University of Medical Sciences
Full name of responsible person
Dr.Fatemeh Faramarzi
Position
Clinical Pharmacy Resident
Other areas of specialty/work
Street address
Sari
City
Sari
Postal code
Phone
00
Fax
Email
faramarzif1984@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
DR Mohammadreza Rafati
Position
Clinical Pharmacist
Other areas of specialty/work
Street address
Sari
City
Sari
Postal code
Phone
00
Fax
Email
rafati293@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Fatemeh Faramarzi
Position
Clinical Pharmacy Resident
Other areas of specialty/work
Street address
Payambar Azam Center Sari
City
Sari
Postal code
Phone
00
Fax
Email
faramarzif1984@gmail.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