Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

Comparison of the effectiveness of maintenance doses of caffeine citrate on tracheal tube removal and apnea after it in premature infants

Protocol summary

Study aim
Comparison of the effectiveness of maintenance doses of caffeine citrate on tracheal tube removal and apnea after it in premature neonates

Design
The clinical trial with parallel groups, one blind strain, randomized in two groups, phase 2-3 is performed on 80 babies. The rand function of Excel software is used for randomization.

Settings and conduct
A single-blind interventional study is conducted on infants hospitalized in the neonatal intensive care unit of Afzalipur Hospital in Kerman, who meet the conditions for entering the study. After the random allocation and receiving the medicine, the babies are examined and the primary and secondary outcomes are checked and recorded.

Participants/Inclusion and exclusion criteria
Entry conditions: neonates with a gestational age of less than 35 weeks and hemodynamic stability during the first 48 hours after mechanical ventilation. Conditions of non-entry: neonates with congenital obstruction and perforation of the gastrointestinal tract, gastroschisis, congenital diaphragmatic hernia, cyanotic heart diseases and other congenital anomalies.

Intervention groups
The first group are infants who are treated with caffeine citrate with an initial dose of 20 mg per kilogram of weight per day and a maintenance dose of 10 mg per kilogram of weight per day until the infant does not experience apnea at least 7 days after extubation. are placed (group with high maintenance dose). The second group are infants who receive caffeine citrate with an initial dose of 20 mg per kilogram of body weight per day and a maintenance dose of 5 mg per kilogram of body weight per day until the infant does not experience apnea at least 7 days after extubation.

Main outcome variables
Tracheal extubation failure and subsequent apnea

General information

Reason for update
End of sampling

Acronym

IRCT registration information
IRCT registration number: **IRCT20230408057850N1**
Registration date: **2023-04-17, 1402/01/28**
Registration timing: **prospective**

Last update: **2023-08-01, 1402/05/10**
Update count: **1**

Registration date
2023-04-17, 1402/01/28

Registrant information

Name
zahra daei parizi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 34 3325 7469

Email address
zdaei@kmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-04-21, 1402/02/01

Expected recruitment end date
2023-07-23, 1402/05/01

Actual recruitment start date
2023-04-21, 1402/02/01

Actual recruitment end date
2023-07-11, 1402/04/20

Trial completion date
2023-07-24, 1402/05/02

Scientific title
Comparison of the effectiveness of maintenance doses of caffeine citrate on tracheal tube removal and apnea after it in premature infants

Public title
Comparison of the effectiveness of maintenance doses of caffeine citrate on tracheal tube removal and apnea after it in premature infants

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Neonates with a gestational age of less than 35 weeks Hemodynamic stability during the first 48 hours after mechanical ventilation

Exclusion criteria:
Neonates with congenital obstruction and perforation of the gastrointestinal tract Gastroschisis Congenital diaphragmatic hernia Cyanotic heart diseases Other congenital anomalies

Age
From **1 day** old to **28 days** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **80**
Actual sample size reached: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
The rand function of Excel software was used for randomization. Based on the random number obtained in the software, the babies are divided into two groups and this process will continue for each group up to 40 people.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, the researcher is informed about the division of groups and the parents have received explanations about the research, but they are not informed about the division of groups. Also, the statistician does not know which data belong to the group with high dose of caffeine.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Kerman University of Medical Sciences

Street address
Imam highway

City
Kerman

Province
Kerman

Postal code
7616913555

Approval date
2023-01-17, 1401/10/27

Ethics committee reference number
IR.KMU.AH.REC.1401.247

Health conditions studied

1

Description of health condition studied
Tracheal tube extubating and subsequent apnea in premature neonates

ICD-10 code
P28.4

ICD-10 code description
Other apnea of newborn

Primary outcomes

1

Description
Tracheal extubation failure and subsequent apnea

Timepoint
During the hospitalization period

Method of measurement
Physical examination

Secondary outcomes

1

Description
Tachycardia

Timepoint
Duration of treatment

Method of measurement
Cardiac monitoring

2

Description
Nutritional intolerance

Timepoint
Duration of treatment

Method of measurement
Physical examination

3

Description
Apnea of prematurity
Timepoint
Before and the end of the intervention
Method of measurement
Physical examination

4

Description
Duration of use of mechanical ventilation
Timepoint
Before and the end of the intervention
Method of measurement
Based on the questionnaire and file information

5

Description
Hospitalization period
Timepoint
Before and the end of the intervention
Method of measurement
Based on the questionnaire and file information

6

Description
Necrotizing enterocolitis
Timepoint
Before and the end of the intervention
Method of measurement
Clinical examination and abdominal imaging

7

Description
Ductus arteriosus remains open
Timepoint
Before and the end of the intervention
Method of measurement
Clinical examination and echocardiography

Intervention groups

1

Description
Intervention group: Caffeine citrate with an initial dose of 20 mg per kilogram of body weight per day and a maintenance dose of 10 mg per kilogram of body weight.
Category
Treatment - Drugs

2

Description
Control group: Caffeine citrate with an initial dose of 20 mg per kilogram of body weight per day and a maintenance dose of 5 mg per kilogram of body weight.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Afzalipur Hospital
Full name of responsible person
Zahra Daei Parizi
Street address
Imam highway
City
Kerman
Province
Kerman
Postal code
7616913355
Phone
+98 34 3132 8000
Email
zdaei@kmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Zahra Daei Parizi
Street address
Imam Highway
City
Kerman
Province
Kerman
Postal code
7616913355
Phone
+98 34 3132 8000
Email
zdaei@kmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Zahra Daei Parizi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

Street address

Imam highway

City

Kerman

Province

Kerman

Postal code

7616913355

Phone

+98 34 3132 8000

Email

zdaei@kmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Zahra Daei Parizi

Position

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Latest degree

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Phone

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Email

zdaei@kmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Zahra Daei Parizi

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Pediatrics

Street address

Imam highway

City

Kerman

Province

Kerman

Postal code

7616913355

Phone

+98 34 3132 8000

Email

zdaei@kmu.ac.ir

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

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Its release schedule is not yet known

When the data will become available and for how long

Its release schedule is not yet known

To whom data/document is available

Its release schedule is not yet known

Under which criteria data/document could be used

Its release schedule is not yet known

From where data/document is obtainable

Its release schedule is not yet known

What processes are involved for a request to access data/document

Its release schedule is not yet known

Comments