

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

zdae@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

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Postal code

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Phone

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Email

zdaei@kmu.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Kerman University of Medical Sciences

Full name of responsible person

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Email

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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

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

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Person responsible for scientific inquiries

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Full name of responsible person

Zahra Daei Parizi

Position

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Person responsible for updating data

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Position

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Latest degree

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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

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