

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Comparison of the effect of caffeine with Aminophylline in treatment of prematurity apnea in preterm neonate (<34 weeks) that admitted in NICU

Protocol summary

Study aim

Comparison of the efficacy and safety of Aminophylline and caffeine in treatment of prematurity apnea

Design

Randomised clinical trial with 2 group that treatment by caffeine in one group and other group treatment by aminophyllin, parallel , double blind , randomised .

Settings and conduct

Randomised clinical trial with 2 group treatment with caffeine 30mg /kg stat and then 15mg/kg /day and other group that treatment with aminophyllin 5mg /kg stat and then 2mg /kg /q8h then 3 days after treatment evaluate for episode of apnea and complication for example hypoglycemi, tachycardia, irritability , seizure, vomiting

Participants/Inclusion and exclusion criteria

neonate with apnea of prematurity and GA less than 34 week that was not due to sepsis , hypoglycemia: BS<50, heart disease and was not intubated .

Intervention groups

Treatment with aminophyllin and treatment with caffeine

Main outcome variables

Recurrence of apnea

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181110041605N1**

Registration date: **2019-01-16, 1397/10/26**

Registration timing: **retrospective**

Last update: **2019-01-16, 1397/10/26**

Update count: **0**

Registration date

2019-01-16, 1397/10/26

Registrant information

Name

Elahe Jafari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3824 3910

Email address

e.jafari@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-06, 1396/12/15

Expected recruitment end date

2018-08-22, 1397/05/31

Actual recruitment start date

2018-03-06, 1396/12/15

Actual recruitment end date

2018-10-07, 1397/07/15

Trial completion date

2018-11-07, 1397/08/16

Scientific title

Comparison of the effect of caffeine with Aminophylline in treatment of prematurity apnea in preterm neonate (<34 weeks) that admitted in NICU

Public title

Comparison of effectiveness of caffeine with Aminophylline in treatment of prematurity apnea in preterm

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Neonate with apnea of prematurity that was GA <34 WEEK

Exclusion criteria:

Neonate with apnea of prematurity that not due to sepsis

,heart disease , hypoglycemi ,was not intuba

Age

From **1 day** old to **10 days** old

Gender

Both

Phase

0

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **80**

Actual sample size reached: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization

Blinding (investigator's opinion)

Double blinded

Blinding description

Researcher , doctors, nurses, data safety and monitoring committee

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Sadoughi university of medical Sciences

Street address

Ebnesina Ave

City

Yazd

Province

Yazd

Postal code

8915887857

Approval date

2018-09-10, 1397/06/19

Ethics committee reference number

IR.SSU.MEDICINE.REC.1397.078

Health conditions studied

1

Description of health condition studied

Apnea of Prematurity

ICD-10 code

J98.9

ICD-10 code description

Respiratory disorder, unspecified

Primary outcomes

1

Description

Recurrence of apnea

Timepoint

72 hours after treatment

Method of measurement

Analysis of recurrence of apnea in 72 hours after treatment

Secondary outcomes

1

Description

Complication of drugs and recurrence of apnea

Timepoint

72 hours after treatment

Method of measurement

Analysis of complication of drugs in 72 hours after treatment

Intervention groups

1

Description

Intervention group: treatment with caffeine

Category

Treatment - Drugs

2

Description

Control group: treatment with aminophillin

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Sadoughi Yazd hospital

Full name of responsible person

Elahe Jafari

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Ebnesina Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Dr Masoud Mirzaei
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e.jafari@ssu.ac.irr
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Yazd 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
Yazd University of Medical Sciences
Full name of responsible person
Elahe jafari
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Pediatrics

Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

No - There is not a plan to make this available