

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Prophylactic aminophylline for prevention of apnea in preterm neonate with weight less than 1200 gr.

Protocol summary

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Summary

A few studies have been done about preventive drugs for apnea of preterm infants so we decided to investigate the prophylactic effects of aminophylline on the apnea incidence in higher risk neonate (preterm neonate with a weight below 1200 grams). In our study the prophylactic effect of aminophylline on the apnea incidence will be investigated in two groups of aminophylline given (group A) and control (group C). In the aminophylline given group (A), after considering the inclusion and exclusion criteria, 5 mg/kg aminophylline as loading dose was begun then each 8 hours, 1/5 mg/kg as maintenance dose was used until first 10 days of life. In control group, no aminophylline was used in first 10 days of life.

Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences, Isfahan, Iran

Expected recruitment start date

2012-03-19, 1390/12/29

Expected recruitment end date

2013-06-24, 1392/04/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013052610026N1**

Registration date: **2013-08-15, 1392/05/24**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-08-15, 1392/05/24

Registrant information

Name

Amir mohammad Armanian

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 1235 5059

Email address

Scientific title

Prophylactic aminophylline for prevention of apnea in preterm neonate with weight less than 1200 gr.

Public title

Prophylactic aminophylline for prevention of apnea in preterm neonate with weight less than 1200 gr.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria are infants born premature and at birth weight equal and lower than 1200 grams and spontaneous breathing at age 24 hours. 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 will excluded.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 52

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

This study is a randomized clinical trial (RCT). Infants admitted to the neonatal intensive care unit (NICU) at Alzahra and Shahid Beheshti hospitals in Isfahan-Iran, will included in this study. The prophylactic effect of aminophylline on the apnea incidence will be investigated in two groups of aminophylline given (group A) and control (group C).

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences,Hezarjerib Av,Isfahan, Iran

City

Isfahan

Postal code

Approval date

2011-08-20, 1390/05/29

Ethics committee reference number

391323

Health conditions studied

1

Description of health condition studied

Apnea

ICD-10 code

P28.3

ICD-10 code description

Primary sleep apnoea of newborn

Primary outcomes

1

Description

Cyanosis

Timepoint

10 days

Method of measurement

nursing documentation and monitor download

2

Description

Bradycardy

Timepoint

10 days

Method of measurement

nursing documentation and monitor download

3

Description

Apnea

Timepoint

10 days

Method of measurement

nursing documentation and monitor download

Secondary outcomes

1

Description

CPAP

Timepoint

10 days

Method of measurement

daily recorded sheets

2

Description

Hospital stay

Timepoint

10 days

Method of measurement

daily recorded sheets

3

Description

Death

Timepoint

During Hospital stay

Method of measurement

daily recorded sheets

4

Description

Mechanical ventilation

Timepoint

10 days

Method of measurement

daily recorded sheets

5

Description

Oxygen dependency time

Timepoint

During Oxygen dependency time

Method of measurement

daily recorded sheets

6

Description

Side effects

Timepoint

10 days

Method of measurement

daily recorded sheets

Intervention groups

1

Description

In the aminophylline given group (A), after considering the inclusion and exclusion criteria for the premature neonate with a weight equal and lower than 1200 gr. who is breathing spontaneously at age 24 hours, 5 mg/kg aminophylline as loading dose will be begun (parenteral) then each 8 hours, 1/5 mg/kg as maintenance dose will be used until first 10 days of life.

Category

Prevention

2

Description

In control group (C), after considering the inclusion and exclusion criteria for the premature neonate with a weight equal and lower than 1200 gr. who is breathing spontaneously at age 24 hours, no aminophylline was used in first 10 days of life.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Neonatal intensive care unit (NICU) at Alzahra and Shahid Beheshti hospitals in Isfahan-Iran

Full name of responsible person

Dr. Amir Mohammad Armanian

Street address

Number 133, shahid ansari Alley, Saeb Street, Isfahan, Iran

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Dr. Ebrahim Esfandiari

Street address

Faculty of Medicine, Isfahan University of Medical Sciences, Hezar-Jerib St., Isfahan, Iran

City

Isfahan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Isfahan 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

Isfahan University of Medical Sciences

Full name of responsible person

Dr. Raha Afghari

Position

Resident of pediatrics

Other areas of specialty/work

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City

Isfahan

Postal code

81638-93113

Phone

+98 31 1630 7533

Fax

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golgoonehafghari@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Child Growth and Development Research Center,
Isfahan University of Medical Sciences

Full name of responsible person

Amir Mohammad Armanian

Position

Neonatologist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Dr. Amir Mohammad Armanian

Position

Assistant professor of neonatology

Other areas of specialty/work

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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