

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Comparing the effect of aminophyllin and caffeine on osteopenia of prematurity in preterm newborns

Protocol summary

Summary

This study is conducted to compare the effect of aminophyllin and caffeine on osteopenia of prematurity in preterm newborns. In a randomized controlled clinical trial, 120 preterm newborn infant with gestation age less than 32 week randomly allocate to aminophyllin or caffeine group. Exclusion criteria include gestation age more than 32 weeks; neonatal neuromuscular disorder, cholestasis, treatment with phenobarbital or corticosteroid, and birth asphyxia. Aminophyllin group receive loading dose of 5mg/kg and then 1-2 mg/kg every 8 hour. Caffeine group will receive 20mg/kg loading dose and then 5-10mg/kg daily. All neonates will receive these drugs till corrected gestation age 34 weeks or becoming apnea free for one week. Neonates will follow for 6 weeks or 45 days after birth to determine calcium, phosphorous and alkanin phosphatase levels and wrist radiography for detection serologic and radiographic evidences of osteopenia of prematurity as our primary outcome. The secondary outcome is broncho-pulmonary dysplasia based on oxygen dependency at 28 days or 36 weeks corrected gestation age.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201312163915N10**
Registration date: **2014-01-20, 1392/10/30**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-01-20, 1392/10/30

Registrant information

Name

Manizheh Mostafa Gharehbaghi

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Tabriz University of Medical Sciences

Expected recruitment start date

2013-12-22, 1392/10/01

Expected recruitment end date

2014-12-22, 1393/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of aminophyllin and caffeine on osteopenia of prematurity in preterm newborns

Public title

Comparing the effect of aminophyllin and caffeine on osteopenia of prematurity in preterm newborns

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: gestation age less than 32 weeks;aminophyllin or caffeine recieption;osteopenia of prematurity survey on 45 days. Exclusion criteria: gestation age over 32 weeks; neonatal neuromuscular

disorder; cholestasis; phenobarbital or corticosteroid therapy; birth asphyxia (apgar score less than 4 at 5 minute).

Age

To **1 year** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committee of Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences; Golgasht street

City

Tabriz

Postal code

Approval date

2013-12-02, 1392/09/11

Ethics committee reference number

92140

Health conditions studied

1

Description of health condition studied

osteopenia of prematurity

ICD-10 code

E83.9

ICD-10 code description

Disorder of mineral metabolism, unspecified

Primary outcomes

1

Description

Osteopenia of prematurity

Timepoint

4 to 6 weeks after bith

Method of measurement

caLcium, phosphorus and alkaLin phospatase measurment

Secondary outcomes

1

Description

Bronchopulmonary dysplasia

Timepoint

28 days after birth and 36 weeks corrected gestation age

Method of measurement

The received FiO2

Intervention groups

1

Description

Administration of intravenous caffein with loading dose of 20 mg/kg and then 5-10 mg/kg from second day of birth till 34 week postmenstrual age to control group

Category

Treatment - Drugs

2

Description

Administration of intravenous aminophylin with loading dose of 3-5 mg/kg and then 1-2 mg/kg from second day of birth till 34 week post menstrual age to intervention group

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

NICU of Alzahra Hospital

Full name of responsible person

Street address

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Tabriz University of Medical Sciences

Full name of responsible person

Dr Rashidi

Street address

Golgasht Street;Tabriz University of Medical Sciences

City

Tabriz

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, Tabriz 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**

Tabriz University of Medical Sciences

Full name of responsible person

Dr Manizheh Mostafa Gharehbaghi

Position

Academic member

Other areas of specialty/work**Street address**

NICU;Alzahra Hospital; South Artesh Street

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Web page address**Person responsible for updating data****Contact****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*