Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

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

Protocol summary

Summary

This study is conducted to compare the effect of aminophylin 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 aminophylin or caffeine group. Exclusion criteria include gestation age more than 32 weeks; neonatal neuromuscular disorder, cholestasis, treatment with phenobarbital or corticosteroid, and birth asphyxia. Aminophylin 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 alkalin 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 aminophylin and caffeine on osteopenia of prematurity in preterm newborns

Public title

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

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: gestation age less than 32 weeks;aminophylin 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
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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