Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

comparing the efficacy of high and low doses of vitamin A in prevention of bronchopulmonary dysplasia in preterm infants

Protocol summary

Summary

In a randomized controlled clinical trial we assess the efficacy of two doses of vitamin A (high and low doses) in prevention of bronchopulmonary dysplasia in preterm infants.One hundred preterm infants with gestation age less than 32 weeks and birth weight less than 1500 grams randomly allocate in two groups based on random number list. Fifty neonates in first group receive 1500 unit intramuscular vitamin A 3 times/ week till forth week of life and 50 neonates in second group receive 5000 unit vitamin A intra muscularly 3 times/ week till 4 weeks of life. All care and drug interventions are same in both groups and nurses and physicians are blind about patient groups.The primary outcome is need for oxygen at 28 days of birth. oxygen dependency is determined by pulse oxymetry and o2 saturation less than 90%. All neonates reassess at 36 weeks corrected gestation age for the severity of bronchopulmonary dysplasia.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201505253915N17**
Registration date: **2015-10-31, 1394/08/09**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-10-31, 1394/08/09

Registrant information

Name

Manizheh Mostafa Gharehbaghi

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1526 2253

Email address

peirovifara@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Research Vice Chancellor of Tabriz University of Medical Sciences

Expected recruitment start date

2015-05-22, 1394/03/01

Expected recruitment end date

2016-05-21, 1395/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparing the efficacy of high and low doses of vitamin A in prevention of bronchopulmonary dysplasia in preterm infants

Public title

comparing the efficacy of two doses of vitamin A in preterm infants

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: prematurity less than 32 weeks; birth weght less than 1500 grams Exclusion criteria: major congenital anomalies; birth asphyxia death before 1 week of life; cyanotic congenital heart disease; intraventricular hemorrhage grade III or more

Age

To **28 days** old

Gender

Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single 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
Golgasht street
City
Tabriz
Postal code
Approval date
2015-05-11, 1394/02/21
Ethics committee reference number
tbzmed.rec.1394.101

Health conditions studied

1

Description of health condition studied
bronchopulmonary dysplasia
ICD-10 code
P27.1
ICD-10 code description
Bronchopulmonary dysplasia originating in the perinatal period

Primary outcomes

1

Description
Bronchopulmonary dysplasia
Timepoint
28 days of life
Method of measurement
need for supplemental oxygen and FiO2

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: intramuscular vitamin A 1500 IU three times/ week from first week of life till 4 weeks.
Category
Treatment - Drugs

2

Description
Intervention group 2: intramuscular vitamin A 5000 IU three times/ week from first week of life till 4 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
NICU; Al Zahra Hospital
Full name of responsible person
Dr Manizheh Mostafa Gharehbaghi
Street address
South Artesh Street
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research Vice Chancellor for Tabriz University of Medical Sciences
Full name of responsible person
Dr Farhoodi
Street address
Golgasht street
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research Vice Chancellor for 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

professor

Other areas of specialty/work

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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