Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of high and low dose of Oral Calcium and Phosphor in Premature and Very Low Birth Weight Neonates

Protocol summary

Summary
We aimed to assess the effects of calcium and phosphor supplementation developing neonatal nephrocalcinosis In this prospective comparative cross sectional study we included 37 premature neonates with births weights <1500g or a gestational age of <34 weeks randomly divided in two groups during 2010-2012. We started Two different oral dosesoral of calcium at low and high doses (75 vs. 230 mg/kg/d)renal sonographic data were then documented and evaluated.

General information

Acronym
Nephrocalcinosis
IRCT registration information
IRCT registration number: **IRCT2013060810441N3**
Registration date: **2013-11-03, 1392/08/12**
Registration timing: **retrospective**

Last update:
Update count: **0**
Registration date
2013-11-03, 1392/08/12

Registrant information
Name
Narjes Pishva
Name of organization / entity
Shiraz University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 71 1612 5481
Email address
pishvan@sums.ac.ir

Recruitment status
Recruitment complete

Funding source
Neonatal research center, Radiology research center

Expected recruitment start date
2010-03-21, 1389/01/01
Expected recruitment end date
2012-03-20, 1391/01/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of high and low dose of Oral Calcium and Phosphor in Premature and Very Low Birth Weight Neonates

Public title
The Effects of Low and High Oral Dose of Calcium and Phosphor Supplementation on Nephrocalcinosis Diagnosed by ultraSonography in Premature and Very Low Birth Weight Neonates
Purpose
Diagnostic
Inclusion/Exclusion criteria
inclusion: We included neonates whose birth weights were less than 1500gr ; gestational age of less than 34 weeks exclusion:Necrotizing enterocolitis or hypercalcemia
Age
From **1 year** old to **6 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **37**

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
Shiraz University Of Medical Science
Street address
Building of Shiraz University Of Medical Science, Zand street, Shiraz
City
Shiraz
Postal code
Approval date
2006-02-14, 1384/11/25
Ethics committee reference number
84-2669

Health conditions studied

1

Description of health condition studied
Nephrocalcinosis
ICD-10 code
N20.0
ICD-10 code description
Urinary calculus, unspecified

Primary outcomes

1

Description
Nephrocalcinosis
Timepoint
30-45-60-120-360 days
Method of measurement
Ultra sonography

Secondary outcomes

empty

Intervention groups

1

Description
Group 1 received oral calcium 75 mg/kg daily and 35mg/kg phosphor daily started 10-15 days after birth or when they can tolerate at least 10 cc oral feeding and continued till 3/5 kg weight
Category
Treatment - Drugs

2

Description
Group two :230 mg/kg per day calcium and 110mg/kg phosphor per day during 10 to 15 days after birth or when they could tolerate 10cc breastfeeding, till 3/5 kg weight
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
the hospitals affiliated to Shiraz University of Medical Sciences
Full name of responsible person
Dr. Pishva
Street address
Fars, Shiraz, Zand street Nemazee Hospital
City
shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Science
Full name of responsible person
Dr. Gholam Reza Hatam
Street address
7th floor dean of research Fars, Shiraz, Zand street building of University Of Medical Science
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz University of Medical Science
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
Shiraz University Of Medical Science
Full name of responsible person
Dr. Narjes Pishva
Position
Professor Of Pediatric, Neonatalogist
Other areas of specialty/work
Street address
Nemazee Hospital, Zand street, Shiraz
City
Shiraz
Postal code
Phone
+98 71 1612 5481
Fax
Email
WWW.pishvan@sums.ac.irwww.marziehdashtpeyma@yahoo.comwww.snrc@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University Of Medical Science
Full name of responsible person
Dr.Narjes Pishva
Position
Professor
Other areas of specialty/work
Street address
Nemazee Hospital Zand street, Shiraz
City
Shiraz
Postal code
Phone
+98 71 1612 5481
Fax
Email
Pishvan@sums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Shiraz University Of Medical Science
Full name of responsible person
Marzieh Dasht peyma
Position
Researcher Of Neonatal Research Center
Other areas of specialty/work
Street address
Neonatal Research Cente, Nemazee Hospital, Zand street
City
Shiraz
Postal code
71937-11354
Phone
+967 116125481
Fax
Email
marziehdashtpeyma@yahoo.com
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