

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 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 doses oral 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, Neonatologist

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City

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Postal code**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