Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Comparison of vitamin D levels after oral and intramascular vitamin D treatment in premature infants with vitamin D deficiency

Protocol summary

Study aim
Choosing the right treatment method to bring the serum vitamin D level to the normal range among preterm neonates

Design
In this study, we have two parallel intervention and control groups that are assigned to treatments by using a block random method using blocks of size 2 (ab and ba). The sample size includes a total of 90 infants, 45 in each group. In this study, the goal is the determination of the effective treatment , therefore, the phase of trial is 3.

Settings and conduct
This study on 90 premature infants will carried on in NICU at Shahid Akbarabadi hospital in Tehran, Iran. No blinding will be performed in this study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Premature infants; with vitamin D deficiency. Non-inclusion criteria: Patients who received vitamin D before the study began; infants with malnutrition; neonates with GFR less than 50; newborns with thyroid disorders.

Intervention groups
Intervention group: Receiving vitamin D by injection. Control group: receiving vitamin D orally.

Main outcome variables
Serum level of Vitamin D

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160120026115N8**
Registration date: **2022-02-26, 1400/12/07**
Registration timing: **registered_while_recruiting**

Last update: **2022-02-26, 1400/12/07**
Update count: **0**

Registration date
2022-02-26, 1400/12/07

Registrant information
Name
Mandana Kashaki
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-11-21, 1399/09/01
Expected recruitment end date
2022-03-20, 1400/12/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of vitamin D levels after oral and intramascular vitamin D treatment in premature infants with vitamin D deficiency

Public title
Comparison of Intramuscular and Oral Vitamin D Treatment in Preterm Infants

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:

All premature infants in the NICU ward Vitamin D level within the range of deficiency.

Exclusion criteria:

Premature infants who received oral or intravenous administration of vitamin D before the start of the study neonates have a malabsorption disease based on clinical presentation neonates with GFR less than 50 neonates with thyroid disorders

Age

From **14 days** old to **28 days** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

In Simple Random Sampling, each element of the target community has an equal chance of being selected. In this study, we used the sampling method using Excel software. In this way, the numbers 1 to 91 using the command: = Randbetween (1.91) That Randbetween is a variable function. This command was given to the software and the software randomly places these numbers in a column as a table of random and random numbers. Then the first 45 are assigned to the first treatment and the second 45 to the second treatment. Random numbers are the same as the number of people entering the study, which are as follows: Random samples extracted in the first group: (15, 61,68,6,37,41,76,23,81,43,56,13,35,10,60,12,51,28,4,17, 71,26,65,38,20 , 33,72,87,82,11, 53,1,91,58,44,85,2,75,67,50,70,45,64,79,46) (48,55,62,36,84,39,49,77,69,47,8,34,22,59,5,83,30,66,5 2,27,19,73,42,18,9 , 24,80,78,88,40,3,7,32,25,57,31,54,21,74,14,29,63,86,16, 90) These numbers are such that the people who enter in numbers 15, 61, 68, etc .; To the first treatment and those who enter 48, 55, 62, etc .; Are assigned to the second treatment. Follow-up of patients on the 16th day after administration of the drug by measurement of vitamin D, calcium, phosphorus and serum alkaline phosphatase. Took

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Iran University of Medical Sciences

Street address

Shaheed Akbarabadi Hospital, Molavi Street

City

Tehran

Province

Tehran

Postal code

1168743514

Approval date

2018-10-28, 1397/08/06

Ethics committee reference number

IR.IUMS.REC.1397.78

Health conditions studied

1

Description of health condition studied

Vitamin D deficiency

ICD-10 code

E55.9

ICD-10 code description

Vitamin D deficiency, unspecified

Primary outcomes

1

Description

serum level in terms of vitamin D

Timepoint

At the beginning of the study and 14 days after treatment

Method of measurement

Lab tests

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intramuscular injection of vitamin D(injection 15000 units per day single dose)

Category

Treatment - Drugs

2

Description

Control group: Prescribing oral vitamin D (oral drops of

1000 units, 1ml daily up to 15 Days)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Akbar Abadi hospital

Full name of responsible person

Mandana Kashaki

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Akbar Abadi Hospital, Molavi Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Leila Irani

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Mandana Kashaki

Position

Neonatologist

Latest degree

Subspecialist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All data is potentially shareable after making individuals unidentifiable
When the data will become available and for how long
The access period starts one year after the results are published.
To whom data/document is available
Researchers working in academic institutions
Under which criteria data/document could be used
The data are allowed for further studies on this research topic.
From where data/document is obtainable
Leila Irani/ Iran University of Medical Sciences/ Iran University of Medical Sciences, Hemmat highway/ or Email address: kashakimd@gmail.com
What processes are involved for a request to access data/document
Written request or email
Comments