# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

25 Oct 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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Iran University of Medical Sciences
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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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Iran University of Medical Sciences, Hemmat highway

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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**

Pediatrics

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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**