# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

26 Jun 2026

## Comparing the effect of different doses of vitamin D supplement on the level of serum 25(OH) vitamin D and bone metabolism related factors in preterm neonates

## Protocol summary

**Study aim**
Evaluation of the effect of different doses of vitamin D supplement on the level of serum 25(OH)vitamin D and bone metabolism related factors in preterm neonates

**Design**
Randomized Clinical trial with parallel groups

**Settings and conduct**
This study is performed on 100 premature infants in Hajar Hospital in Shahrekord. At the beginning of the study blood samples are taken from all the infants for checking Calcium, Phosphorus, 25 Hydroxy Vitamin D, and Alkaline Phosphatase levels.These babies are divided into 2 groups of fifty. Groups Are being unified based on type of residence, rural and urban, as well as vitamin D level.The onset of vitamin D prescription in newborns begins when breastfeeding has reached 150 cc/kg. The first group receives 400 and the second group receives 800 units of vitamin D daily.The treatment is continued until Modified age 40 weeks after LMP, and in this time the mentioned lab tests are cheked again.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: gestational age 28 to 34 weeks; the absence of major disorders and malformations; the absence of systemic diseases, such as asphyxia and cholestasis. Exclusion criteria: supportive nutrition for more than 2 weeks; use of anticonvulsant and anti HIV drugs by the infant's mother; use of injectable vitamin D during the study; formula feeding; nephrocalcinosis in the infant.

**Intervention groups**
The amount of 300 units of vitamin D is given to Infants in two groups through FMS supplement and then received vitamin D reaches 400 and 800 units per day with the use of two types of vitamin D drops . The first group: 100 units of A + D drop (Behsa) plus distilled water. The second group: 100 units of A + D drop(Behsa) plus 400 units of vitamin D drop 1000 units per cc (vitabiotics).

**Main outcome variables**
Levels of vitamin D; calcium; phosphorus; alkaline phosphatase

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20171030037093N4**
Registration date: **2019-03-03, 1397/12/12**
Registration timing: **registered_while_recruiting**

Last update: **2019-03-03, 1397/12/12**
Update count: **0**

**Registration date**
2019-03-03, 1397/12/12

**Registrant information**

**Name**
Sadra Ansaripour

**Name of organization / entity**
Shahrekord University of Medical Sciences

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Iran (Islamic Republic of)

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2018-07-25, 1397/05/03

**Expected recruitment end date**
2019-07-25, 1398/05/03

**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Comparing the effect of different doses of vitamin D supplement on the level of serum 25(OH) vitamin D and bone metabolism related factors in preterm neonates

**Public title**
Effect of vitamin D supplementat on the level of serum vitamin D in preterm neonates
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Gestational age between 28 and 34 weeks The absence of major disorders and malformations The absence of systemic diseases, such as asphyxia and cholestasis
**Exclusion criteria:**
Supportive nutrition for more than 2 weeks Use of anticonvulsant and anti HIV drugs by the infant's mother Use of injectable vitamin D during the study Formula feeding Nephrocalcinosis in the infant
**Age**
From **1 day** old to **30 days** old
**Gender**
Both

**Phase**
2-3
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **100**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Cases are randomized using random allocation through the software. In this way, after the selection of 100 preterm infants that have the inclusin criterias, neonates are randomly assigned to one of the two intervention groups by statistical software.
**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 Shahrekord University of Medical Sciences
**Street address**
Vice chancellor for research, Building No. 2, University headquarters, Ayatollah Kashani Blvd
**City**
Shahrekord
**Province**
Chahar-Mahal-va-Bakhtiari
**Postal code**
8815713492
**Approval date**
2018-06-24, 1397/04/03
**Ethics committee reference number**
IR.SKUMS.REC.1397.100

## Health conditions studied

**1**

**Description of health condition studied**
Vitamin D deficiency in premature infants
**ICD-10 code**
E55
**ICD-10 code description**
Vitamin D deficiency

## Primary outcomes

**1**

**Description**
Serum level of 25 hydroxy vitamin D
**Timepoint**
Beginning of study, Modified age 40 weeks after LMP
**Method of measurement**
Blood sample

**2**

**Description**
Serum level of calcium
**Timepoint**
Beginning of study, Modified age 40 weeks after LMP
**Method of measurement**
Blood sample

**3**

**Description**
Serum level of Phosphorus
**Timepoint**
Beginning of study, Modified age 40 weeks after LMP
**Method of measurement**
Blood sample

**4**

**Description**

Serum level of Alkaline phosphatase

**Timepoint**

Beginning of study, Modified age 40 weeks after LMP

**Method of measurement**

Blood sample

## Secondary outcomes

**1**

**Description**

**Timepoint**

**Method of measurement**

## Intervention groups

**1**

**Description**

Intervention group: reciving 300 units of vitamin D through FMS supplement plus 100 units of A + D drop ( 400 unints per cc , Behsa) plus distilled water

**Category**

Treatment - Drugs

**2**

**Description**

Intervention group: reciving 300 units of vitamin D through FMS supplement plus 100 units of A + D drop ( 400 unints per cc , Behsa) plus 400 units of vitamin D drop (1000 units per cc vitabiotics)

**Category**

Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Hajar Hospital

**Full name of responsible person**

Nasim Rahimi

**Street address**

Hajar Hospital,Nursing Street ,Kashan Blvd,Shahrekord City,Chahar Mahal and Bakhtiari

**City**

Shahrekord

**Province**

Chahar-Mahal-va-Bakhtiari

**Postal code**

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**Phone**

+98 38 3222 0016

**Email**

Hajar-Hospital@skums.ac.ir

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Shahre-kord University of Medical Sciences

**Full name of responsible person**

Dr. Seyed Kamal Solati

**Street address**

Vice chancellor for research, Building No. 2, University headquarters, Ayatollah Kashani Blvd

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**Phone**

+98 38 3334 2414

**Email**

kamal_solati@yahoo.com

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Shahre-kord 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**

Shahre-kord University of Medical Sciences

**Full name of responsible person**

Roya Choopani

**Position**

Assistant Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Pediatrics

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Position**

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**Latest degree**

Subspecialist

**Other areas of specialty/work**

Pediatrics

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**Phone**

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**Email**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be 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**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available

**Title and more details about the data/document**

Information about the main outcome can be shared.

**When the data will become available and for how long**

Start the access period 4 months after publishing the results

**To whom data/document is available**

Researchers working in academia

**Under which criteria data/document could be used**

Use data to complete clinical trial studies

**From where data/document is obtainable**

Hajar Hospital in Shahrekord, nasim18r@yahoo.com

**What processes are involved for a request to access data/document**

after the investigation of resercher request and presentation of required documents will be accessible.

**Comments**