Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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Chahar-Mahal-va-Bakhtiari

Postal code

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Phone

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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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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

Contact

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Position

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Person responsible for updating data

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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